Tackling malnutrition in Residential Aged Care (RAC) with a new compact Oral Nutritional Supplement (ONS)

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Jessica Jellicoe

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Abstract

Background: Malnutrition has several negative health consequences for older adults. Nutrition interventions using oral nutritional supplements (ONSs) are part of the solution and outcomes may be enhanced with the Medication Pass Nutrition Supplement Program (Med Pass).

Aim: To determine whether 60 ml of a new compact ONS consumed four times daily with the medication round (Med Pass protocol) for 18-weeks is effective in improving nutrition status, physical strength (hand grip strength) and quality of life (QoL) measures. A secondary aim was to determine levels of compliance to the compact ONS following the Med Pass protocol.

Methods: An 18-week, pilot intervention study was undertaken among 20 residential aged care (RAC) residents (mean age: 86.65 ± 6.8 y; 50 % female) assessed as being malnourished or at risk of malnutrition using the Mini Nutritional Assessment-short form (MNA-SF). Residents received 4x60 ml ONS (576 kcal/ml and 35 g protein) daily with the medication round. ONS intake and participant compliance were recorded daily. BMI, fat, and muscle mass (Bioelectrical Impedance Analysis [BIA]), grip strength (handgrip dynamometer), nutrition risk (MNA-SF), QoL (SF-12 tool) and depressive symptoms (Geriatric Depression Scale [GDS-15]) were assessed at baseline and at post intervention.

Results: Median overall compliance was 98.6%. Median nutrition status (MNA-SF scores) improved by 10% (+1 [-1 , 1], *p=0.197, d*=0.288) along with a mean increase in body weight (1.5 ± 5.9 kg , *p*=0.259*, d*=0.260) and muscle mass (0.8 ± 2.2 kg, *p*=0.137 *, d*=0.390). Improved scores for SF-12 physical (+ 5.9 ± 11.1) and mental (2.8 ± 12.0) components and depressive symptoms (-1 [-3.5, 1.0]) were also observed.

Conclusion: We found compliance to a new nutrient- and energy dense ONS using the Med Pass protocol was 98.6 %, demonstrating its acceptability among RAC residents. We observed an improvement in nutrition risk status, weight, muscle mass, GDS-15 score and SF-12 score. Providing nutrient and energy dense ONS using the Med Pass protocol may be an effective method of improving nutrition status in RAC residents and warrants further investigation among a larger group of RAC residents.

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Contents

List of Abbreviations

BIA- Bioelectrical Impedance Analysis

BMI- Body Mass Index

DHB- District Health Board

DXA- Dual-energy X-ray Absorptiometry

ESPEN- European Society for Clinical Nutrition and Metabolism

EQ-5D-European Quality of Life Five Dimension

GDS-15-Geriatric Depression Scale-15

MCS- Mental Component Summary

Med Pass- Medication Pass Nutrition Supplement Program

MNA- Mini Nutritional Assessment

MNA-SF- Mini Nutrition Assessment-Short Form

MUST- Malnutrition Universal Screening Tool

ONS- Oral Nutritional Supplement

PCS- Physical Component Summary

QoL – Quality of Life

RAC- Residential Aged Care

RCT- Randomised Control Trial

RDI- Recommended Daily Intake

SF-12- Medical Outcomes Study 12-item Short Form Health Survey

SF-36- Medical Outcomes Study 36-item Short Form Health Survey

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Chapter 1: Purpose

The population of older adults in New Zealand is increasing. In 2016, 15% of the population was aged over 65 years. By 2046, this will increase to 21-26% with the fastest growing segment of the older population being adults of advanced age (85 years and older) (Statistics New Zealand, 2016). These later years of life can often be of low quality due to frailty and disease (Walker, 2007).

To maintain a good quality of life (QoL) with age it is important that older adults maintain their functional ability and can perform basic self-care activities independently. These activities are referred to as activities of daily living and include eating, bathing, and dressing (Covinsky et al., 2003). Loss of independence in these activities is strongly associated with a deterioration in mental and physical health, the need for residential aged care (RAC), as well as higher health care costs and mortality (Fortinsky, Covinsky, Palmer, & Landefeld, 1999).

Malnutrition defined as 'a state in which a deficiency of nutrients such as energy, protein, vitamins and minerals causes measurable adverse effects on body composition, function or clinical outcome (National Institute for Health and Care Excellence, 2017) ' in older adults is also an issue. In the older adult population malnutrition results in negative changes in body composition (unintentional weight loss, decreased muscle mass and sarcopenia), worsening health outcomes, impaired physical function, reduced QoL, and increased hospitalisations and mortality rates (Chatindiara, Williams, et al., 2018; Lee, Tsai, & Wang, 2015; Splett, Roth-Yousey, & Vogelzang, 2003; Volkert et al., 2019). Loss of independence and malnutrition are linked as loss of independence increases difficulty in procuring, preparing and eating food independently, while malnutrition can further reduce functional ability. In a New Zealand study, a high prevalence of malnutrition (47%) was found among older adults at early entry to RAC (Wham et al., 2017). This prevalence was higher than among older adults admitted to hospital (23%) and those living in the community (2%) (Wham et al., 2017). Of older adults admitted to RAC within the Waitemata District Health Board (DHB) region, most (91%) were identified to be at nutritional risk, with 47% identified as 'malnourished' and 43% as 'at risk of malnutrition' (Watkin, 2014). These findings highlight that older adults are likely to be at increased nutritional risk at admission to a RAC facility.

The Australian and New Zealand Society for Geriatric Medicine position statement regarding undernutrition and the older person states that it is important that older people are screened and assessed for malnutrition (Australian & New Zealand Society for Geriatric Medicine, 2019). Malnutrition screening on admission and regularly during RAC residency is likely to improve identification of malnutrition risk and enable timely nutrition intervention to improve nutrition status (Lee et al., 2015; Meijers, Tan, Schols, & Halfens, 2014; Watterson, Fraser, Banks, & Isenring, 2009).

Early intervention is crucial, as while nutrition interventions benefit older adults *at risk* of malnutrition, it is suggested they are relatively ineffective for older adults who are already malnourished (Lee et al., 2015; Lee et al., 2013; Porter Starr, McDonald, & Bales, 2015). Identifying malnutrition risk and implementing a nutrition intervention is necessary to avoid an irreversible decline in health.

In RAC settings, nutrition interventions that fall under the 'food first' approach are typically implemented first by providing fortified meals and snacks (e.g. adding milk powder to meals and providing cheese and crackers as a snack. If the food fortification intervention does not result in an improvement in nutritional or clinical outcomes, the use of oral nutrient supplements (ONS) is recommended (Volkert et al., 2019). ONS are products typically in liquid form that contain amounts of energy and nutrients in a smaller volume than would normally be acquired from food (Uí Dhuibhir, Collura, & Walsh, 2019). Use of ONS as a nutrition intervention has resulted in multiple positive outcomes in RAC worldwide (Lauque et al., 2000; Manders et al., 2009; Parsons, Stratton, Cawood, Smith, & Elia, 2017; Turic, Gordon, Craig, Ataya, & Voss, 1998). These outcomes include weight gain, improved nutritional status, improved QoL and increased energy, protein and micronutrient intake (Lauque et al., 2000; Manders et al., 2009; Parsons et al., 2017; Turic et al., 1998).

The benefit of ONS for RAC residents is dependent on resident compliance to the ONS regime. In a 12-week trial of 87 residents in German RAC, participants were administered 125 ml ONS (300 kcal) twice daily between meals. High levels of compliance were associated with significant weight gain, improved BMI and improved levels of nourishment, while low compliance was associated with weight loss (Jobse et al., 2015), highlighting the importance of compliance to an ONS regime. Mean compliance to ONS across 52 studies was calculated to be 78.2% across health care settings (Hubbard, Elia, Holdoway, & Stratton, 2012). The main ONS related factor positively associated with compliance was high energy density (≥ 2 kcal/ml) with a pooled mean overall compliance among eight studies of 91% (Hubbard et al., 2012). A trial of 200 acute aged care patients in Switzerland who received either 60 ml of a 2 kcal/ml ONS four times daily or a mid-meal ONS of energy density ranging from 1.05-1.5 kcal/ml found compliance was high (95%) in the 2 kcal/ml ONS group, compared with the group receiving the less nutritionally dense ONS (48%) (Jukkola & MacLennan, 2005). These studies suggest that higher energy density ONS provided outside of mealtimes is needed for increased levels of compliance.

The Med Pass protocol is designed to produce high rates of compliance to ONS. The protocol involves distributing small doses (60 ml) of energy dense ONS between meals, three or four times daily during the medication round (Canadian Agency for Drugs and Technologies in Health, 2015). In an eight-week uncontrolled clinical trial completed by 49 older patients in a Canadian orthopaedic trauma unit, participant and staff acceptance of Med Pass was investigated. Participants were found to enjoy taking

ONS with their medications and staff stated that Med Pass decreased their overall workload (Dillabough, Mammel, & Yee, 2011). Positive perceptions of Med Pass from staff and participants suggest that compliance to ONS is less likely to be impacted by unmotivated staff or participant burden. Improving and maintaining nutritional status and increasing compliance to ONS interventions are key factors to optimise health among RAC residents.

Among residents in a RAC facility identified at risk of malnutrition the aim of this study was to determine whether 60 ml of a new compact ONS consumed four times daily with the medication round (the Med Pass protocol) for 18 weeks is effective in improving nutrition status, physical function and QoL measures. A secondary aim of the study was to determine levels of compliance to the compact ONS Med Pass protocol.

The objectives of this study were to:

Objective one: among RAC residents identified as at risk of malnutrition or malnourished using the Mini Nutrition Assessment-Short Form (MNA-SF), identify muscle and fat mass using Bioelectrical Impedance Analysis (BIA) scales, weight and height using electronic scales and a height stadiometer, strength using a grip strength dynamometer, depressive symptoms and QoL using the Geriatric Depression Scale-15 (GDS-15) and SF-12 tool.

Objective two: determine the overall volume, energy, and protein content of ONS consumed by participants over the 18-week trial.

Objective three: determine levels of compliance to the ONS protocol by monitoring whether residents consumed the ONS four times daily, the amount that was consumed and any reasons for not consuming the full amount.

Objective four: assess whether providing older adults identified to be at risk of malnutrition or malnourished with a new compact ONS over the 18-week trial improves weight, nutrition status, muscle and fat mass, strength (hand-grip strength), depressive symptoms and QoL.

The hypothesis for this study is that providing RAC residents identified to be at risk of malnutrition or malnourished with a new compact ONS four-times daily over 18 weeks will reduce rates of malnutrition.

This thesis is written following thesis guidelines provided for students enrolled in the MSc Nutrition and Dietetics program and is divided into four chapters. The first chapter provides context to the issue of increasing numbers of the population reaching older age without maintaining good health or functional ability. This chapter highlights the importance of good nutritional status and the prevention

of malnutrition in older adults and sets out the aims and objectives of the study. The second chapter critically reviews literature relating to the health and nutrition status of older adults and interventions that can be utilised to maintain and or improve nutritional health of older adults. The third chapter is presented as a manuscript of the study that will be submitted to *Nutrition & Dietetics*, the journal of Dietitians Australia, and includes the results and outcomes from the 18-week ONS intervention study. The fourth and final chapter is a discussion of the findings of the study, an overview of the achievement of the aims and objectives of the study and whether the hypothesis was met. This final chapter also includes strengths and limitations of the research, an explanation of the impact of the study and final recommendations.

Table 1. Table indicating all contributors and their roles

Contributor	**Roles**
Professor Carol Wham	Main Supervisor
Dr Wendy O'Brien	Main Supervisor
Dr Hajar Mazahery	Statistician
Amy Richter	Research Assistant
Brittany Malcolm	Research Assistant
Phillipa Darroch	Research Assistant
Mariam Hanosh	Research Assistant

Chapter 2 Literature Review

Ageing in New Zealand

By 2050 it is predicted that the number of people aged over 65 years will double, resulting in 20% of the global population being classed as older adults (United Nations, 2019; World Health Organisation, 2016). Older adults can be split in two categories the youngest old, those aged 65-85 years and the oldest old, those aged 85 years and over (Broad et al., 2011; Kerse, Lapsley, Moyes, Mules, & Edlin, 2016). Currently in New Zealand, around 15% of the population is aged 65 and over. This is expected to increase to 21-26% by the year 2046, with the number of people who are aged 85 and over expected to triple by the year 2043. Thus the oldest old is the most rapidly growing age group in New Zealand (Kerse et al., 2016; Statistics New Zealand, 2016).

Currently, these extra years of life can be of low quality as they are often hampered by frailty and disease (Walker, 2007). Evidence of the impact can be seen in the New Zealand DHBs spending, with 42% of the budget spent on the older population despite over 65s only making up 15% of the New Zealand population. Without improvement in the health of older adults, DHB spending will only increase as more of the population reach older age (Ministry of Health, 2016). This is a global phenomenon with older adults in the USA using the greatest proportion of health care services despite making up only 14% of the population (Porter Starr et al., 2015).

The New Zealand Ministry of Health has developed the Healthy Ageing Strategy with the goal of ensuring older adults spend more of their lives in good health and living independently (Associate Minister of Health, 2016). This is of great importance as, while the majority of older adults are independent and living within the community (Kerse et al., 2016), RAC funding still makes up 60% of DHB spending for older adults (Ministry of Health, 2016). If demand for RAC increases at the same rate as the older adult population, funding will not be sustainable (Ovseiko, 2007). To prevent a further increase in spending it is necessary for older adults to remain healthy and independent enabling them to remain in their own homes.

Body composition changes with age

For older adults to remain living independently their functional ability must be maintained, ensuring that they are still able to perform basic self-care activities. These activities are referred to as activities of daily living and include activities such as eating without assistance, bathing, and dressing (Covinsky et al., 2003). Unintentional weight loss, sarcopenia (age related loss of muscle mass) and decreased muscle mass are common negative body composition changes associated with ageing (Hickson, 2006;

Porter Starr et al., 2015). Decreased functional ability is an outcome of these changes (Brownie, 2006) and may compromise the ability of adults to live and carry out activities of daily living independently.

As well as decreased functional ability there are other negative outcomes of body composition changes associated with ageing. A review carried out to investigate the management of unintentional weight loss in older adults surmised that weight loss of more than 4% within a year or more than 10% over 5-10 years is associated with increased morbidity and/or mortality (Alibhai, Greenwood, & Payette, 2005). In a study carried out in New Mexico, age differences in body composition and anthropometry were investigated. The body composition of 316 men and women aged 60 to 95 years were assessed using dual energy X-ray absorptiometry (DXA) and isotope dilution methods. The study found that on average older adults lost 6-7% of their fat free mass between the ages of 65-85 years despite relative weight stability, health and good levels of activity (Baumgartner, Stauber, McHugh, Koehler, & Garry, 1995). In a four-year observational study carried out in the United States weight and body composition changes of 2163 older adults aged 70-79 years, were observed. It was found that men losing weight lost 5.8% of their lean mass and 10.8% of their fat mass, whilst weight gain resulted in a 2.0% increase in lean mass and 17.9% increase in fat mass. In women weight loss was found to result in a 5.0% decrease in lean mass and 12.7% decrease in fat mass and weight gain was found to result in 3.0% increase in lean mass and 13.7% increase in fat mass (Newman et al., 2005). These findings demonstrate that in older adults' changes in fat mass are greater than lean mass in both weight loss and weight gain and that lean mass lost with weight loss is proportionally greater than lean mass gained with weight gain. Suggesting that weight loss, even if it is followed by weight gain increases the risk of sarcopenia.

Unintentional weight loss (resulting in low BMI) and decreasing muscle mass are both indicators of the beginning of sarcopenia (Broadwin, Goodman-Gruen, & Slymen, 2001; Evans & Campbell, 1993; Zhang et al., 2019). Sarcopenia is associated with a decline in muscle strength, disability, falls, loss of independence and a reduced QoL (Goodpaster et al., 2006; Hwang et al., 2020). In a snapshot study of 91 older adult participants carried out in 3 Auckland RACs, prevalence of sarcopenia was found to be 41%. Risk factors associated with sarcopenia were low BMI and a MNA score indicating risk of malnutrition/malnutrition (Darroch, 2021). In a 2-year cohort study carried out in Japan, 743 community dwelling older adults were assessed and it was found that sarcopenia was associated with functional decline (Tanimoto et al., 2013). Slowing or preventing these changes in body composition has the potential to have a positive impact on these outcomes that can compromise QoL and functional ability.

Nutritional health of older adults

Good nutritional health in older adults is associated with maintenance of physical function and prevention of malnutrition (Ministry of Health, 2013). For good nutritional health the nutritional needs of older adults need to be met. Physical inactivity, body composition and physiological changes associated with ageing impact hunger and, feelings of satiety, along with nutrient intake, absorption, and utilisation (Porter Starr et al., 2015). As a result, the nutritional needs of older adults differ from their younger counterparts (Ministry of Health, 2013). For older adults' total energy requirements decrease while protein, vitamin and mineral requirements are the same or increase (Elmadfa & Meyer, 2008; Porter Starr et al., 2015). These changes increase the risk of protein and micronutrient deficiencies which have a negative impact on the nutritional health and physical function of older adults.

Protein intake is of particular importance for the maintenance of functional and health status in older adults (Volpi et al., 2013), as protein is vital in the maintenance of muscle mass at any age. Evidence-based recommendations endorsed by the Australian and New Zealand Society of Geriatric Medicine state that for older adults to maintain and regain muscle mass average daily protein intake should be 1.0 to 1.2 g protein per kilogram of body weight per day. Protein requirements for older adults with acute and chronic disease increase even further (1.2g-1.5 g/kg body weight/day) (Bauer et al., 2013). This is reflected in the current nutrient reference values for protein which increase from the age groups 51-70 years to 71+ years (Ministry of Health, 2006). Within these age groups, the recommended daily intake (RDI) for protein increases from 0.75 g protein/ kg body weight/ day to 0.94 g/kg body weight/ day in women and from 0.84 g/kg body weight/day to 1.07 g/kg body weight/ day in men (Ministry of Health, 2006). Despite these recommendations, findings from the Adult Nutrition Survey 2008-09 show that protein intake decreases as older adults move from the age groups 51-70 years and 71+ years, with average protein intake decreasing by 20 g in males and 9 g in females (University of Otago and Ministry of Health, 2011). These findings demonstrate that as older adults age they may be eating less protein despite having increased protein requirements. A consequence of inadequate protein in older age is that the decline in muscle mass and function associated with ageing is likely to occur more rapidly than if an adequate protein intake was being consumed (Porter Starr et al., 2015).

Reduction in energy intake is one of the main causes of declining nutritional health in older adults (Ministry of Health, 2013). In 2011, the most recent Adult Nutrition Survey completed in New Zealand found that as older adults moved from the 51-70 year to 71+ years age group energy intake in females decreased by 260 kcal and male intake decreased by 312 kcal (University of Otago and Ministry of Health, 2011). While this decrease in energy intake may be in response to a decrease in energy

expenditure associated with ageing, when the decrease in energy intake is greater than the decrease in energy expenditure weight loss is the result (MacIntosh, Morley, & Chapman, 2000).

Decreased dietary intake can be a consequence of psychosocial, physical, and physiological influences. Psychosocial influences on dietary intake include poverty, loneliness, social isolation and depression, all of which can result in significant loss of appetite (Donini, Savina, & Cannella, 2003). Physical influences include poor dentition, swallowing difficulties both of which increase eating difficulty and low levels of physical activity which can reduce appetite (Donini et al., 2003; Pirlich & Lochs, 2001). Physiological impacts on dietary intake include earlier satiety due to slowed stomach emptying and a reduced stomach capacity, limiting the amount of food that is eaten over the day. Also polypharmacy, with various medications reducing appetite and altering the taste of foods limiting their acceptability (Elmadfa & Meyer, 2008). If dietary intake is reduced significantly and/or over a long period of time, malnutrition is likely to occur.

Malnutrition

There is no universal definition of clinical malnutrition, with each definition appropriate for differing settings and population groups. The National Institute for Health and Care Excellence provides the definition most appropriate for malnutrition in older adults. This definition states that 'Malnutrition is a state in which a deficiency of nutrients such as energy, protein, vitamins and minerals causes measurable adverse effects on body composition, function or clinical outcome' (National Institute for Health and Care Excellence, 2017). Clinical malnutrition in older adults' results in negative changes in body composition, worsening health outcomes, impaired physical function, reduced QoL, and increased hospitalisations and mortality rates (Chatindiara, Williams, et al., 2018; Lee et al., 2015; Splett et al., 2003; Volkert et al., 2019). Protein-energy malnutrition will deplete muscle protein and muscle strength, reducing physical function further (Lee et al., 2015). Due to these negative consequences the Aged Residential Care Service review funded by the DHBs, identifies nutrition support, and therefore the prevention of malnutrition as one of the medical specialities required to maintain the health of older adults (Grant Thornton NZ Ltd., 2010).

In a New Zealand study of 167 older adults, prevalence of malnutrition in various settings was assessed (Wham et al., 2017). The highest prevalence of malnutrition was found in those who had been recently admitted to RAC when compared to recent hospital admission or living in the community (47% vs 23% vs 2%. respectively) (Wham et al., 2017). In a snapshot study within Waitemata DHB region, of the 53 participants (mean age: 88 years), 47% participants identified were identified 'malnourished' and 43% at 'risk of malnutrition' (Watkin, 2014). These findings suggest that the setting in which older adults require the most nutrition support is RAC.

Older adults entering RAC have been found to have had a significant decline in physical function and nutritional status (Chatindiara et al., 2020), both of which have the potential to increase rates of malnutrition. Once in RAC there are several further barriers to improved nutritional status which include lack of independence, co-morbidities and having no autonomy over when and what they can eat (Holmes, 2006). Without nutritional intervention, nutritional health of vulnerable older adults is unlikely to improve after admission to RAC.

Screening for malnutrition

Despite worldwide rates of malnutrition in RAC residents reported to be 40-70%, malnutrition is not being recognised and is being left untreated (Watterson et al., 2009). Malnutrition screening on admission and regularly during RAC residency is likely to improve identification of malnutrition risk and enable a timely nutrition intervention to be put in place (Lee et al., 2015; Meijers et al., 2014; Watterson et al., 2009). Timely intervention is crucial as while nutrition interventions benefit older adults at risk of malnutrition, it is suggested to be relatively ineffective for older adults who have already reached a state of malnutrition (Lee et al., 2015; Lee et al., 2013; Porter Starr et al., 2015). This highlights the benefit of identifying and treating older adults before the risk of malnutrition transitions to malnutrition and results in an irreversible decline in health.

Given the importance of malnutrition screening, especially in the RAC setting, appropriate malnutrition screening tools must be carefully selected. Various tools are available for this purpose, including the Mini Nutritional Assessment (MNA), MNA-SF, Malnutrition Universal Screening Tool (MUST), Simplified Nutritional Appetite Questionnaire and the Simple Nutrition Screening Tool (Watterson et al., 2009). The criteria of these screening tools are BMI and or change in weight along with various other nutritional risk factors (Porter Starr et al., 2015).

Use of the MNA-SF is often recommended as it efficiently identifies the most nutritional risk factors, is validated for use in older adults and is quicker to administer than the full MNA (Chatindiara, Allen, et al., 2018; Porter Starr et al., 2015). The MNA-SF consists of six items: BMI, recent weight loss, stress or acute disease, mobility, neuropsychological problems, loss of appetite and difficulty eating. The results of these items are then scored to indicate an individual's nutritional status; 'malnourished' (score 0-7), 'at risk of malnutrition' (score 8-11), or 'normal nutrition status' (score 12-14) (Kaiser et al., 2009).

The MNA-SF has been used to assess nutrition status of older adults across various settings in New Zealand (Buhs-Catterall, 2014; Watkin, 2014). Use of the MNA-SF identified nutrition risk among 81% in older adults in Assessment, Treatment and Rehabilitation Wards in North Shore and Waitakere hospitals, with 23% of participants identified as 'malnourished' and 58% identified as 'at risk of

malnutrition' (Buhs-Catterall, 2014). In the RAC setting use of MNA-SF identified nutrition risk of 91% in older adults admitted to RAC within Waitemata DHB region with 47% participants identified as 'malnourished' and 43% at 'risk of malnutrition'(Watkin, 2014). These New Zealand based findings suggest that in the RAC setting older adults are at an increased nutritional risk.

Nutrition interventions to tackle malnutrition

An appropriate nutrition intervention has several benefits that include reduced cost of health care, improved nutritional and clinical outcomes, and prompt improvements in the negative consequences of malnutrition (Gallagher, Voss, Finn, & McCamish, 1996; National Collaborating Centre for Acute Care, 2006). In RAC, nutrition interventions that fall under the 'food first' approach are typically implemented first. This includes increasing number of snacks provided to residents and/or food fortification (increasing the energy and/or protein content of meals, typically without increasing meal volume).

Implementation of the 'food first approach' in RAC has been found to significantly increase protein and energy intake (Iuliano, Woods, & Robbins, 2013), increase weight (Leslie et al., 2013) and improve body composition and nutritional markers (Smoliner et al., 2008). These changes were brought about by fortifying foods that were familiar to participants e.g. bread and milk (Beelen, de Roos, & de Groot, 2017; van Til et al., 2015) and adding dairy products e.g. adding cream and milk powder to meals (Gall, Grimble, Reeve, & Thomas, 1998; Iuliano et al., 2013; Smoliner et al., 2008). However not all 'food first' interventions are successful. In a study carried out in a RAC in South Florida where breakfast and lunch meals were fortified there was no significant increase in protein intake (Castellanos, Marra, & Johnson, 2009). Low lactose milk powder was used to fortify the meals of residents of a RAC in Hong Kong for seven weeks. Despite nearly 100% compliance to the fortification regime there was no significant increase in weight (Kwok, Woo, & Kwan, 2001). When significant improvements are not achieved through a food first approach, nutrition interventions should progress onto the use of ONSs (Volkert et al., 2019).

ONSs are products usually in liquid form that are used to improve nutritional intake when diet alone does not meet nutritional needs. They contain amounts of energy and nutrients in a smaller volume than would normally be in food and are available in various energy densities (with >1.5 kcal/ml considered to be 'high energy') and with differing protein content (with >20% of energy from protein classified as 'high protein') (Volkert et al., 2019). Although use of ONSs have been found to result in increased energy intake and QoL in comparison to the food first approach (Parsons et al., 2017; Turic et al., 1998), the 'food first approach' should be implemented initially. This is due to it being the cheaper intervention and more likely to be accepted over a long period of time. Long term acceptance

of an intervention is highly important in RAC, as residents' median length of stay is more than a year (Central Region Technical Advisory Services Limited, 2019). As the food first approach and ONSs have differing benefits, best practice is to use them in conjunction with each other (Volkert et al., 2019).

Oral nutrient supplements (ONSs)

There are several organisations which provide guidelines for the use of ONSs. The National Institute for Health Care Excellence created the guidelines 'Nutrition support for adults: nutrition support, enteral tube feeding and parenteral nutrition' (National Institute for Health and Care Excellence, 2017). The guidelines suggest ONSs should only be considered for adults who can swallow safely and are malnourished or at risk of malnutrition.

Dietitians Australia have produced evidence based practice guidelines for the nutritional management of malnutrition in adult patients across the continuum of care (Watterson et al., 2009). These guidelines recommend that the individual prescription should be based on the gap between oral intake and nutritional requirements and nutrition support should be continued for a significant timeframe. Providing ONSs with mealtimes should be avoided, while administering ONSs with medication round can facilitate adherence and a supportive environment is encouraged to enhance compliance.

The European Society for Clinical Nutrition and Metabolism (ESPEN) provide guidelines on clinical nutrition and hydration in geriatrics (Volkert et al., 2019) which seek to prevent and/or treat malnutrition. ESPEN recommend that various interventions are trialled e.g., meal time assistance, providing finger food. If these interventions are not sufficient ONSs should be offered to increase dietary intake. ESPEN recommended that ONSs should provide 400 kcal/day with at least 30 g/day of protein and should be continued for at least one month. Compliance to ONSs should be regularly assessed and adaptations made in regard to timing, taste and texture to meet patient's taste and eating capacities.

Support for ESPEN recommendations come from a six month-prospective multicentre observational study of 191 older adults in France, investigating risk of hospitalisation and health care costs when ONSs were provided. It was found that risk of hospitalisation was 2.5 times lower with ONSs providing $\geq$400 kcal/day and three times lower with $\geq$30 g/day protein when compared to no supplementation (Seguy et al., 2020). Thus, showing that following ESPEN recommendations could not only reduce rates of malnutrition but also reduce hospitalisation and therefore the healthcare costs of older adults.

There are multiple studies that have investigated the benefit of ONSs in older adults (Table 2). Evidence suggests that to address malnutrition, 6-12 weeks of 300-600 kcal with/without 16 g-23 g

protein of ONS daily is required (Gazzotti et al., 2003; Lauque et al., 2000; Smith, Cawood, Walters, Guildford, & Stratton, 2020). As expected, increased weight and energy intake were also outcomes of these studies as these are the measures used within malnutrition screening tools.

Weight gain is the most common outcome of studies investigating use of ONSs in older adults, with the increase ranging from 0.12-5.2 kg (Chapman et al., 2009; Lauque et al., 2000; Lee et al., 2013; Manders et al., 2009; Parsons et al., 2017; Pouyssegur et al., 2015; Smith et al., 2020; Wouters-Wesseling et al., 2005). Weight gain of 5.2 kg occurred in a one-year uncontrolled clinical trial of 49 community dwelling older adults (Chapman et al., 2009), which suggests that the study outcome (weight gain) was achieved. However, weight alone does not account for changes in body composition. Most of the weight gained by participants in the study by Chapman et al (2009) was fat mass, while lean body mass decreased. Increasing fat mass and decreasing lean body mass in older age are associated with numerous negative outcomes which include physical impairment and increased dependence in activities of daily living while maintenance/increasing lean body mass can prevent these outcomes (Hickson, 2006; Volkert et al., 2019). These findings highlight the need to assess body composition, and not just weight gain when determining effectiveness of supplementation and supplementation protocol.

Improved QoL and/or physical and social function were the outcome of studies reviewed in Table 2(Gariballa & Forster, 2007; Lee et al., 2015; Parsons et al., 2017). Gariballa and Forster (2007) used the Medical Outcomes Study 36-item Short Form Health Survey (SF-36) to assess QoL and found ONSs resulted in significant improvements in physical and social function. It is suggested that these improvements are brought about by improvements in micronutrient status, specifically vitamin B12 and folate levels, as deficiencies of these micronutrients have been linked to geriatric depression which is associated with a decline in physical and social function (Fiske, Wetherell, & Gatz, 2010; Tiemeier et al., 2002). This emphasises that the micronutrient content of ONSs, as well as the protein and energy content, produce positive outcomes in older adults.

It has been proposed that use of ONSs has a suppressive effect on appetite and displaces actual food intake (Kayser-Jones et al., 1998). This is undesirable as once RAC residents become adequately nourished, ONSs will no longer be provided for them. Multiple studies have found that ONS has little suppressive effect on appetite and food intake and the majority of ONS energy is additive to food (Gariballa & Forster, 2007; Loman et al., 2019; Smith et al., 2020; Turic et al., 1998). In fact, a two-month prospective randomised control trial (RCT) carried out among 80 older adults in a Belgium hospital found that spontaneous dietary intake was significantly higher in the ONS group when compared to the control group (Gazzotti et al., 2003). A six-week RCT carried out in a French RAC

found that appetite steadily increased during the ONS intervention and had continued in the 12-week post intervention follow up (Pouyssegur et al., 2015). This suggests that ONS may not only be additive to dietary intake but could also increase dietary intake.

The success of a nutrition intervention is highly dependent on the awareness and motivation of staff (Pirlich & Lochs, 2001). A qualitative study in UK RACs found that most staff did not view providing ONS to be an additional workload. However, over the six-month protocol, staff compliance dropped from 100% to 95% during the third month (Stow, Ives, Smith, Rick, & Rushton, 2015). An explanation for the reduction in compliance is that over a period residents start to refuse ONS and require more staff time to convince them to consume the ONS, thus creating a larger burden on staff (Simmons, Zhuo, & Keeler, 2010). This highlights the need to assess patient requirements to ensure that they actually do require ONS, and staff are not burdened with convincing patients who do not want to take the ONS and also do not need them.

A summary of the outcomes of the studies that have used ONS as a nutrition intervention for older adults is provided in Table 2. Interventions were implemented across several settings: in RAC, in the community and the hospital. Several benefits of ONS as a nutrition intervention are evident.

Table 2. Outcomes of studies using ONS as a nutrition intervention.

Reference	Design	Intervention	Participants	Outcomes
(Lauque et al., 2000)	60-day, Prospective RCT	ONS product (300-500 kcal) + regular meals three-day dietary record assessed. MNA scores and anthropometry assessed	N=88 Residents in French RAC	Decreased malnutrition (increased MNA from 13.9±2.6 to 17.1±3.9), weight gain (+1.5±0.4 kg), significant increase in energy intake (+411.5 kcal).
(Smith et al., 2020)	12-week, RCT	ONS + dietary advice. Encouraged to consume at least 600 kcal and 16 g protein daily from ONS for at least 12-weeks. MUST scores, EQ-5D tool, anthropometry and 3-day food record assessed.	N=308 Free living older adults in the UK.	Decreased malnutrition, weight gain(+0.8 kg), improved QoL (EQ-5D increased by 1.9±0.9 units), increased energy intake and protein intake (+401 kcal, +15 g/d) and no suppressive effect on appetite. Reduced healthcare care use (health care professional visits by 34%, emergency admissions 50%, length of stay 62%). High levels of compliance (83%).
(Turic et al., 1998)	6-week, RCT	Facility diet + ONS (300 kcal, 15 g protein) three times daily. Three-day food record assessed.	N=91 Residents from four RACs in the USA	Increased energy intake (+592 kcal), protein (+30 g/day), and micronutrient intake. No suppressive effect on appetite

(Manders et al., 2009)	24-week, RCT	ONS (125 ml, 1 kcal/ml) twice daily + usual diet Biochemical markers and anthropometry assessed.	N=176 Residents from nine RACs in the Netherlands	Weight gain (+1.4 kg), Increased intake of micronutrients: Vitamin D, Homocysteine, Folate, Vitamin B12, Vitamin B6
(Wouters-Wesseling et al., 2005)	6-month, RCT	ONS (125 ml, 1 kcal/ml, 3.5g protein/100 ml) twice daily Anthropometry assessed.	N=68 RAC residents in the Netherlands	Weight gain (+1.6 kg)
(Gariballa & Forster, 2007)	6-week, RCT	Normal hospital diet + ONS (200 ml, 2.5 kcal/ml) twice daily SF-36 results and validated food diary assessed.	N=225 Hospitalized acutely ill older patients in the UK	Improved QoL specifically in physical function (7.0 treatment effect), social function (7.8 treatment effect) and role physical (10.2 treatment effect) domain scores. No suppressive effect on appetite.
(Lee et al., 2015)	24-week, RCT	ONS 50 g/day (9.5 g protein, 250 kcal) Barthel Index score and handgrip strength assessed. Institution records of hospital utilisation assessed.	N=92 RAC residents in Taiwan	Increased independence in activities of daily living (Barthel Index score +0.9). Reduced healthcare utilizations: no. of outpatient visits (-0.16 visits) and length of stay (-7.17 days) when compared to control group. Increased handgrip strength (+1.04 kg).
(Lee et al., 2013)	24-week, RCT	ONS 50 g/day (9.5 g protein, 250 kcal) Weight, BMI, mid-arm and calf circumference assessed.	N=92 RAC residents in Taiwan	Increased body weight (0.12 $\pm$ 2.62 kg), BMI (+0.07 $\pm$ 1.06 kg/m2), mid-arm

				circumference (0.17 ± 1.02 cm), calf circumference (0.43 ± 1.44 cm).
(Parsons et al., 2017)	12-week, RCT	Aiming to increased ad libitum intake of ONS by at 600 kcal and 16 g protein each day. Anthropometric measures and assessment of QoL (EQ-5D-3L). 24 hour diet recall and 24hour diet history assessed.	N=104 RAC residents in the UK	Improved QoL (0.50 ± 0.04 units), significant weight increase (+1.22 ± 0.45 kg) and significant increase in protein (+9.8 g) and energy intake (+286 kcal).
(Heyman, Van De Looverbosch, Meijer, & Schols, 2008)	9-week, open multicentre trial	Recommended dose ONS (200 ml, 250 kcal, 20 g protein) three times daily	N=245 RAC residents Luxembourg and Belgium	Practitioners stated they would continue to use ONS. Patients accepted ONS three times daily
(Stow, Smith, & Rushton, 2018)	30-60min interviews at 3 and 6-months of intervention	ONS taken twice daily (volume not provided, 600 kcal, 24 g protein)	N=4 RAC residents N=12 members of staff	Staff stated that implementing ONS did not create an additional work load. Patients stated that ONS was acceptable
(Loman et al., 2019)	3-month, RCT	ONS (237 ml, 350 kcal, 20 g protein) twice daily. 24-hour dietary recall assessed.	N=30 Older patients discharged from hospital in USA.	Micronutrient (iron, magnesium, phosphorus, zinc, copper, manganese, selenium, vitamin A, vitamin B12, choline) intake increased to meet or exceed nutrient intake goals, no suppressive effect on appetite

(Tidermark et al., 2004)	6-month, RCT	ONS (200 ml, 20 g protein, no kcal mentioned) once daily The Index of Activities of Daily Living and DXA assessed.	N=60 Older free-living women, in Sweden	Maintained activities of daily living at a high level but declined significantly in control group. Lean body mass was maintained but declined in control.
(Chapman et al., 2009)	1-year, uncontrolled clinical trial	ONS (80 ml, 160 kcal) three times daily with meals encouraged. Anthropometric assessment and strength assessed using hand dynamometer. MNA scores assessed.	N=49 Community dwelling older adults at risk of malnutrition/malnourished	Weight gain (+5.2 $\pm$ 1.5). Increased grip strength (+2.5 $\pm$ 1.25). Decreased malnutrition (+3 $\pm$ 0.7units).
(Gazzotti et al., 2003)	60-day, prospective RCT	ONS (200 ml, 250 kcal, 11.5 g protein) twice daily. MNA scores, food diary of ONS and spontaneous intake and anthropometry assessed.	N=80 Hospitalised older adults in Belgium until a couple of days after discharge	Decreased malnutrition (+3.4 units), weight gain (+0.28 $\pm$ 3.8 kg) . Spontaneous intake of kcal (+443 kcal) and protein (+15.3 g) was significantly higher in ONS group when compared to control group.
(Seguy et al., 2020)	6-month, Prospective multicentre observational study.	ONS prescribed according to GP usual practice. Short MNA scores, anthropometry, direct health care costs (provided by GPs) assessed.	N=191 Malnourished community living older adults, living in France.	Health care costs significantly reduced when energy intake from ONS >500 kcal/day.

				Risk of hospitalisation significantly reduced when intake from protein ONS was >30 g/day.
(Pouyssegur et al., 2015)	6-week, RCT	ONS (cookie form, 52 g, 244 kcal, 11.5 g protein). Anthropometry and dietary intakes measured.	N=154 Residents in a French RAC	Weight gain (+1.6%), appetite steadily increased.

Abbreviations

RCT-Randomised Control Trail

ONS- Oral Nutrient Supplement

MNA-Mini Nutritional Assessment

MUST- Malnutrition Universal Screening Tool

EQ-5D-European Quality of Life Five Dimension

QoL- Quality of Life

RAC- Residential Aged Care

SF-36- Medical Outcomes Study 36-item Short Form Health Survey

BMI-Body Mass Index

DXA- Dual-energy X-ray Absorptiometry

Compliance

The benefits of ONSs can only be achieved if residents consume the product provided and are compliant to the ONS regime. This is demonstrated in a 12-week RCT in a German RAC, in which high levels of compliance were associated with significant weight gain, improved BMI and levels of nourishment while low compliance was associated with weight loss (Jobse et al., 2015). Additionally, a 28-day RCT of female patients admitted to a hospital in Perth which had significant issues with participant compliance (Bruce, Laurance, McGuiness, Ridley, & Goldswain, 2003) resulted in similar rates of weight loss in the control and intervention group of the study. Issues with compliance were due to patient reluctance or inability to take ONS. It is noted that the participants who were more compliant in the intervention group lost significantly less weight.

There are several methods that can be used to measure compliance. Counting the number of cans that have been consumed (Bruce et al., 2003; Collins, Kershaw, & Brockington, 2005), calling participants and asking them to recall their levels of compliance (Chapman et al., 2009) and weighing leftover supplement (Allen, Methven, & Gosney, 2014; Jobse et al., 2015). Another method to assess compliance is to engage the nursing staff who provide the ONS. For example in a 60-day trial carried out in a RAC in France with each supplement provided nursing staff noted down how much of the ONS was consumed (none, ¼, $^{1}/_{2}$, ¾, all) (Lauque et al., 2000). Measuring compliance in this way has a high reliance on RAC staff so it is essential that staff are aware and on board with the intervention.

A systematic review of compliance to ONS found that overall mean compliance was 78% (37-100%), with higher energy density ONS associated with greater compliance (Hubbard et al., 2012). A four-week, RCT of 50 older adults attending health centres in the UK supports this association. Compliance in a group receiving 1 kcal/ml was 91% compared to 95% in the 2 kcal/ml group (Collins et al., 2005). The compliance in both these groups is excellent and higher than average (78%) (Hubbard et al., 2012). Not only was compliance higher in the 2 kcal/ml group, but more importantly, this group was receiving a more energy and nutrient dense supplement, so received twice the nourishment as the 1 kcal/ml group.

Evidence suggests that compliance is higher when ONSs are served in a form that cognitively declined RAC residents (who make up the majority of RAC residents (Jobse et al., 2015)) are familiar with. In a 12-month RCT residents were provided with an ONS either in a glass/beaker or given the ONS bottle with a straw in it. Compliance was highest when the ONS was provided in a glass/beaker (Allen et al., 2014). It is suggested that this is due to the residents being able to recognise that it is something for them to drink. Also serving ONS in a glass allowed nursing staff to gage clearly how much has been

consumed and potentially provide residents with encouragement to consume more. This would have been harder to do for ONS in their opaque bottles (Allen et al., 2014).

In a repeated measures study in which 21 community-dwelling older adults visited a laboratory on three occasions and rated what they thought of various foods and ONS, it was found that free-living older adults found ONS to be pleasant (McAlpine, Harper, McMurdo, Bolton-Smith, & Hetherington, 2003). This could suggest that older adults enjoy the taste of ONS. However in a 28-day quasi-RCT of older female patients admitted to a hospital in Perth, dislike of the taste of ONS was one of the main reasons given by participants for low levels of compliance (Bruce et al., 2003). A potential reason for the differing findings of these studies is the older adults in hospital were consuming ONSs every day for 28 days and were likely to experience flavour fatigue while the community-dwelling older adults were not. To combat issues with compliance due to disliking the taste of ONS it suggested that residents should be able to choose from a variety of different flavours (Hubbard et al., 2012). This provides, older adults with autonomy and also reduces the risk of flavour fatigue.

Table 3 provides a summary of studies that assessed compliance to ONS. These studies show that good compliance brings about numerous positive outcomes; weight gain/maintenance, improved BMI, reduced levels of malnutrition (Gazzotti et al., 2003; Jobse et al., 2015).

Table 3. Outcomes of studies assessing compliance to ONS

Reference	Design	Intervention	Participants	Outcomes
(Bruce et al., 2003)	28-day, Quasi-RCT.	ONS (235 ml, 1.5 kcal/ml, 352 kcal, 17.6g protein) once daily Compliance assessed by counting cans consumed	N=109 older female patients admitted to Perth hospital with BMI range 20-30 kg/m^2	Increased levels of compliance (% not defined) resulted in significantly less weight loss Disliking ONS taste was main reason for very low compliance.
(Chapman et al., 2009)	1-year, uncontrolled clinical trial	ONS (80 ml, 2 kcal/ml, 160 kcal) three times daily with meals encouraged. Compliance assessed by phone call every 2 weeks.	N=49 Community dwelling older adults at risk of malnutrition/malnourished	High levels of compliance (87.8%)
(Collins et al., 2005)	4-week, RCT	ONS (237 ml, 1 kcal/ml, 252 kcal, 8.8 g protein or 237 ml, 2 kcal/ml, 475 kcal, 19.8 g protein) once daily Encouraged to consume 80 ml 3x with meals. Compliance assessed from mean total of cans consumed.	N=50 Older patients attending health centres in the UK	Compliance was less in 1 kcal/ml group (91%) compared to the 2 kcal/ml (95%) group.
(Allen et al., 2014)	12-month, RCT (RCT).	ONS three times daily provided on alternate days via straw directly from the container or given in a glass/beaker. Compliance assessed by weighing any leftover ONS.	N=45 Cognitively impaired UK RAC and hospital residents	Compliance was higher for ONS served from glass/ beaker (64.6% vs. 57.3%).

(Jobse et al., 2015)	12-week, RCT	ONS (125 ml, 300 kcal) twice daily between meals. Compliance assessed by nursing staff who registered amount of supplement consumed and weighing leftover ONS.	N=87 RAC residents in German	Median compliance was 72.9% and exclusion of residents who dropped out of the study increased compliance to 82%. High compliance was associated with significant weight gain, improved BMI, and an increase in MNA-SF score while low compliance was associated with weight loss. Compliance was increased by motivated ward staff
(Lauque et al., 2000)	60-day, RCT	Provided ONS variety of ONS (300-500 kcal) of resident's choice. Each portion of supplement was measured by direct observation and recorded as all, $^{3}/_{4}$, $^{1}/_{2}$, $^{1}/_{4}$ or none of the portion.	N=88 RAC residents in France	Good compliance with all products in each nursing home.
(Gazzotti et al., 2003)	60-day, prospective RCT.	ONS (200 ml, 250 kcal, 11.5 g protein) twice daily. Compliance assessed through direct observation and recorded as, all, $^{3}/_{4}$, $^{1}/_{2}$, $^{1}/_{4}$ or none of the portion.	N=80 Hospitalised older adults in Belgium until a couple of days after discharge	Good compliance- supplement consumed everyday by participants

Abbreviations

RCT- Randomised Control Trial

ONS- Oral Nutrient Supplement

BMI-Body Mass Index

RAC-Residential Aged Care

MNA-SF- Mini Nutritional Assessment-Short Form

Medication Pass Nutrition Supplement Program (Med Pass)

The Med Pass protocol involves distributing small amounts (60 ml) of energy dense ONS in between meals, during medication rounds, three or four times daily (Winnipeg Regional Health Authority, 2015). This protocol has been utilised across RAC and hospital settings (Dillabough et al., 2011; Jukkola & MacLennan, 2005; Remsburg, Sobel, Cohen, Koch, & Radu, 2001; Roberts, Potter, McColl, & Reilly, 2003) for several reasons. Use of an energy dense ONS is associated with greater compliance and increased protein and energy intake when compared to standard ONS (Collins et al., 2005; Hubbard et al., 2012). Also providing ONS along with medication increases efficiency of ONS provision (Canadian Agency for Drugs and Technologies in Health, 2015).

A RCT investigating Med Pass was carried out in a New South Wales RAC centre over a nine-month period (Jukkola & MacLennan, 2005). Results from the qualitative staff questionnaire indicated that using Med Pass was not more time-consuming that usual practice and that having the ONS order written in the medication chart assisted in monitoring residents' intake. It was suggested by the authors that a further benefit of having the ONS charted with medication highlighted the importance of nutrition in residents' treatment plans. These findings show that staff have positive perceptions of the Med Pass suggesting that its implementation would have the support of staff and will therefore not be limited by unmotivated staff.

An eight-week uncontrolled clinical trial of 49 older patients in a Canadian Orthopaedic trauma unit interviewed patients and staff to assess their views on the Med Pass protocol. Staff stated that the use of Med Pass decreased their workload and most patients enjoyed consuming their ONS with their medications. Patients also stated that they did not notice any reduction in their appetite during the study (Dillabough et al., 2011). Patient acceptance of an ONS protocol is of great importance, as if they consider it too burdensome, they are less likely to be compliant thus mitigating any benefits of ONS.

As well as acceptance from staff and residents/patients the Med Pass protocol is associated with increased weight, energy and protein intake, high levels of compliance and improved QoL among older adults in RAC and hospitals in Australia, Canada and USA (Campbell, Webb, Vivanti, Varghese, & Ferguson, 2013; Jukkola & MacLennan, 2005; Remsburg et al., 2001; Roberts et al., 2003; Welch, Porter, & Endres, 2003). Positive outcomes of studies which have utilised the Med Pass protocol are described in Table 4.

Table 4. Outcomes of studies using Med Pass Protocol

Reference	Design	Intervention	Participants	Outcomes
(Remsburg et al., 2001)	3-month, pre- and post-test design.	ONS (60 ml, 120 kcal, 4.8 g protein) three/four times daily distributed at drug round. Anthropometric measures, estimated uneaten portions of food and results from staff survey assessed.	N=17 RAC residents	Pre-study weight was maintained. Energy intake from food increased (+19%), while energy intake from ONS decreased (-29%) and total energy intake decreased (obtained from both food and ONS, -17%). Positive staff perceptions of Med Pass.
(Roberts et al., 2003)	Blinded RCT	ONS (120 ml, 180 kcal, 7.5 g protein), provided in medicine cup given three times daily and distributed at medication round. Weighted food diary, compliance and staff questionnaire assessed.	N=381 Admissions to older adult medicine department	Total energy intake was significantly increased (*P*=0.023) and good compliance (>80%) was observed. Positive staff perceptions of Med Pass.
(Jukkola & MacLennan, 2005)	RCT	ONS (60 ml, 120 kcal, 5 g protein) given four times daily. Anthropometric measures, nursing records of actual food consumption and ONS compliance, specific	N=200 New South Wales RAC residents	Excellent compliance (95%). Significant increase in protein intake (+19g /day). Increased energy intake (+451 kcal). Improved nutrition status (2.58 improved score)

		findings from MNA and findings from staff qualitative questionnaire assessed.		Significant decrease in length of stay compared to control (22.85 days vs. 35.75 days). Positive staff perceptions of Med Pass
(Dillabough et al., 2011)	8-week, uncontrolled clinical trial	ONS (60 ml, 126 kcal, 5.06 g protein) given three times daily with medication round. Doses of Med Pass, food intake and staff and patient interviews were assessed.	N= 49 Older patients in Alberta Canada, Orthopaedic trauma unit	High levels of compliance (91.4%) Positive staff perceptions of Med Pass
(Welch et al., 2003)	2-weeks baseline assessment, 4 week, uncontrolled clinical trial.	ONS (60 ml, 120 kcal, 5 g protein) four times daily distributed at medication round. Anthropometric measures and three-day dietary intake assessed.	N=30 RAC residents in the USA	Significant increase in weight (+2.46 kg). Average intake for main meals increased (+7 %), greatest increase at evening meals (+16 %).
(Campbell et al., 2013)	2-week, RCT	ONS (60 ml, 120 kcal, 5 g protein) given four times daily with medication round. Anthropometric measures, three-day food diaries, EQ-5D questionnaire assessed.	N=74 Malnourished patients in geriatric and rehabilitation wards in Queensland	Increased weight (+1.5 kg) Patients significantly more likely to meet their protein and energy requirements (110-126% requirements met). Significant improvement of QoL rating (12.4 score improvement).

Abbreviations

ONS- Oral Nutrient Supplement

RAC-Residential Aged Care

Med Pass- Medication Pass Nutritional Supplement Program

RCT-Randomised Control Trial

MNA-Mini Nutritional Assessment

EQ-5D-European Quality of Life Five Dimension

QoL- Quality of Life

Summary

While there have been significant increases in the longevity of older adults, QoL and health continue to decline in the last years of life (Walker, 2007). Reduced functional ability, negative body composition changes associated with ageing and older adults not meeting their nutritional needs are all contributing to this decline (Brownie, 2006; Hickson, 2006; Volkert et al., 2019). Body composition changes and nutritional needs of older adults are linked; nutrition intervention has the potential to postpone and slow body composition changes and in turn slowed body composition changes meaning that functional ability is more likely to be maintained. Maintained functional ability allows older adults to meet their nutritional needs by continuing to prepare food, cook and feed themselves increasing the likelihood that their nutritional needs be met.

If nutritional needs are not met for a long period of time, malnutrition may occur. Malnutrition increases the risk of mortality and morbidity in older adults (Splett et al., 2003; Volkert et al., 2019). With appropriate screening tools malnutrition can be identified and timely nutrition interventions can be put in place. Malnutrition screening identified RAC as the setting where risk of malnutrition is highest (Watkin, 2014; Wham et al., 2017). After the use of the 'food first approach', ONSs are the nutrition intervention that is usually implemented in RAC. ONSs can bring about multiple benefits to older adults in RAC which include reduced rates of malnutrition, increased weight, increased lean mass and improved QoL (Parsons et al., 2017; Turic et al., 1998).

Benefits of ONSs can only be brought about if older adults are compliant to the ONS regime (Jobse et al., 2015). Compliance can be increased through motivated nursing staff and using energy dense ONSs (Collins et al., 2005; Hubbard et al., 2012; Jukkola & MacLennan, 2005). The Med Pass protocol builds on this by providing 3-4 60 ml of doses energy dense ONSs with the medication round (Winnipeg Regional Health Authority, 2015). Use of the medication round relays the importance of nutrition support to RAC residents and staff and has been found to increase compliance and save staff time (Canadian Agency for Drugs and Technologies in Health, 2015; Jukkola & MacLennan, 2005). Evidence suggests that use of energy dense ONS following the Med Pass protocol could reduce rates of malnutrition among older adults in RAC in New Zealand.

Chapter 3 Research Study Manuscript: Tackling malnutrition with a new compact oral nutrient supplement (ONS) among residents in a Residential Aged Care facility.

Abstract

Background: Malnutrition has several negative health consequences for older adults. Nutrition interventions using oral nutrient supplement (ONS) are part of the solution and outcomes may be enhanced with the Med Pass protocol.

Aim: To determine whether 60 ml of a new compact ONS consumed four times daily with the Med Pass protocol for 18-weeks is effective in improving nutrition status and physical strength (grip strength) and QoL measures. A secondary aim was to determine levels of compliance to the compact ONS following the Med Pass protocol.

Methods: An 18-week, pilot intervention study was undertaken among 20 RAC residents (mean age: 86.65 ± 6.8 y; 50 % female) assessed as being malnourished or at risk of malnutrition using the MNA-SF. Residents received 4x60 ml ONS (daily providing 240 ml of ONS, 576 kcal and 35 g protein) daily with the medication round. ONS intake and participant compliance were recorded daily by RAC staff on a tracking sheet. BMI, fat and muscle mass (BIA), grip strength (handgrip dynamometer), nutrition risk (MNA-SF), QoL (SF-12 tool) and depressive symptoms (GDS-15) were assessed at baseline and at post intervention.

Results: Median overall compliance was 98.6%. Median nutrition status (MNA-SF scores) improved by 10% (+1 [-1, 1], *p=0.197, d*=0.288) along with a mean increase in body weight (1.5 ± 5.9 kg, *p*=0.259*, d*=0.260) and muscle mass (0.8 ± 2.2 kg, *p*=0.137*, d*=0.390). Improved scores for SF-12 physical (+ 5.9 ± 11.1) and mental (2.8 ± 12.0) components and depressive symptoms (-1 [-3.5, 1.0]) were also observed. Despite these improvements there were no significant changes (*p*=<0.05) and effect size was small (*d*=0.2).

Conclusion: Delivery of a compact ONS using Med Pass was largely accepted by residents and may be an appropriate intervention to improve nutrition risk status, weight, muscle mass, depressive symptoms and mental and physical wellbeing among RAC residents.

Key words: older adults, malnutrition, residential aged care, energy-dense oral nutritional supplement, Med Pass

Introduction

Malnutrition in older adults may lead to a loss of body weight and muscle mass, and impaired physical function, as well as adverse health outcomes and decreased QoL (Lee et al., 2015; Splett et al., 2003; Volkert et al., 2019). A previous investigation in New Zealand found that 47% of older adults entering RAC were malnourished and 43% were at risk of malnutrition (Wham et al., 2017), highlighting the need for effective nutrition risk screening and intervention.

It is well established that malnutrition screening on admission and at regular intervals during stays in RAC, increase the likelihood of malnutrition risk being identified, and enables timely implementation of appropriate interventions (Lee et al., 2015; Meijers et al., 2014). While a 'food first approach' (e.g., provision of extra snacks and fortified meals) is the preferred first step to improve nutrition status, the use of ONSs is recommended when the food first approach does not meet nutritional needs (Volkert et al., 2019). ONSs are products usually in liquid form that are used to improve nutritional intake when diet alone does not meet nutritional needs. They contain amounts of energy and nutrients in a smaller volume than would normally be in food and are available in various energy densities (with >1.5 kcal/ml considered to be 'high energy') and with differing protein content (with >20% of energy from protein classified as 'high protein') (Volkert et al., 2019). In a 12-week RCT among 104 RAC residents in the UK, use of ONS significantly increased protein and energy intake, increased weight and reduced risk of malnutrition (Parsons et al., 2017). In this RCT, residents were encouraged to consume a 600 kcal, 16 g protein ad libitum intake of ONS daily, which resulted in mean increased daily intake of energy (286 kcal) and protein (9.8 g) and increased body weight (1.2 kg) (Parsons et al., 2017). In France, a 60-day prospective RCT among residents in RAC found provision of ONS (300-500 kcal/day) along with regular meals resulted in a mean increase in MNA score of 3.2 points (Lauque et al., 2000). Similar interventions providing 250-1000 kcal/day in the form of ONS have also reported increases in energy, protein and micronutrient intake, and weight. Improved QoL and physical and social function have also been reported over 6-24 weeks in several studies among acutely ill older adults in the UK, older patients discharged from hospital in USA and older residents in RACs in the Netherlands and the USA (Gariballa, Forster, Walters, & Powers, 2006; Loman et al., 2019; Manders et al., 2009; Turic et al., 1998; Wouters-Wesseling et al., 2005).

To achieve the benefits associated with ONS, compliance with the ONS regime is needed. In a 12-week RCT in Germany 87 RAC residents were administered 125 ml ONS twice daily (providing 600 kcal) between meals (Jobse et al., 2015). High levels of compliance (≥80%) were associated with significant weight gain, improved BMI and an increase in MNA-SF score (Jobse et al., 2015). By contrast, low compliance (≤30%) among residents was associated with weight loss (Jobse et al., 2015). Use of energy dense ONS (>2 kcal/ml) has been found to increase levels of compliance. In a double-blinded RCT in

the UK, 50 older adults with poor wound healing who consumed 80 ml of ONS three times a day, were found to have a mean compliance of 91% among those receiving 1 kcal/ml and 95% compliance in those receiving 2 kcal/ml (Collins et al., 2005).

The Med Pass protocol is an ONS regime that utilises energy dense ONS and is associated with high levels of compliance. The protocol involves distributing small doses (~60 ml) of energy dense ONS (≥2 kcal/ml) during the medication round, three or four times daily in between meals (Canadian Agency for Drugs and Technologies in Health, 2015). In Australia, a RCT utilising the Med Pass protocol among older hospitalised adults found compliance to be excellent at 95%, along with a significant improvement in appetite, increased consumption of meals, protein intake and weight, and decreased length of stay in hospital (Jukkola & MacLennan, 2005). It was also found that adding ONS to the normal medication round was no more time consuming for staff and resulted in less ONS wastage. Further studies utilising the Med Pass protocol carried out in RACs in Canada, USA and Australia reported high levels of compliance, positive staff perceptions, significant weight increases, increased intake of main meals and a significant improvement in QoL (Campbell et al., 2013; Dillabough et al., 2011; Welch et al., 2003).

While the benefits of providing a compact, energy dense ONS using Med Pass protocol among RAC residents have been shown internationally, the effects of such a regime have not been explored in RAC facilities in New Zealand. The aim of this pilot study was to determine whether use of a compact ONS using the Med Pass protocol can reduce malnutrition risk and improve health and social wellbeing among RAC residents in New Zealand.

Methods

An open pilot intervention study was conducted among residents at an Auckland RAC facility. Residents from rest home and hospital level of care who met the inclusion criteria were invited to participate. The inclusion criteria were: MNA-SF score 0-11 (malnourished or at risk of malnutrition), aged ≥65 years, BMI <30 kg/m^2 and deemed eligible to participate by judgement of the RAC clinical manager. Residents with a pacemaker were included in this study but were unable to complete the body composition assessments using bioimpedance scales.

Residents were recruited between April and June 2021. An Information Sheet and consent form (Appendix B) was provided and explained directly to the residents or their EPOA, with the opportunity to ask questions about the study procedure. Of 50 residents who met the eligibility criteria, 32 provided consent to participate. Ethical approval for this study was gained from Health and Disability Ethics Committee (Ref. 20/NTB/120).

Participant characteristics

Socio-demographic and health data were collected at baseline from the clinical notes and included residents' gender, age, ethnicity, marital status, highest level of education, prior living setting, level of care, comorbidities, and number of prescribed medications. Anthropometric measures; hand-grip strength, MNA-SF score, GDS-15 score and QoL (SF-12) score were assessed at baseline and at post intervention.

Height was measured to the nearest 0.1 cm using a portable stadiometer (SECA, 213 model, Hamburg, Germany). For non-weight bearing residents ulna length was measured to the nearest 0.5 cm and validated equations were used to predict height (Barbosa, Stratton, Lafuente, & Elia, 2012). Weight was measured to the nearest 0.1 kg using portable electronic scales (SECA GMBH & Co., 813 model, Hamburg, Germany). Non-weight bearing residents were weighed to the nearest 0.1 kg in the RAC's calibrated chair hoist. Muscle mass and fat mass were indirectly measured using portable BIA (InBodyS10, Inbody Co, Ltd., Seoul, Korea), following the protocol in the InBody S10 user manual as closely as possible (In Body Co, Ltd 2014). While the BIA does not directly measure muscle mass, it is a validated measure of lean body mass with intraclass correlation coefficients of 0.96 for men and 0.95 for women when compared with DXA scans (Ling et al., 2011). BIA measurements were taken while residents were in a supine or reclined position. Hand grip strength was assessed as a physical measure using a hand dynamometer (Jamar, model #5030J1, Sammons Preston, USA). Residents were seated with their elbows at a 90-degree angle. Residents squeezed the dynamometer as tightly and for as long as possible until the needle stopped rising. This process was repeated three times with each hand and results recorded to the nearest 1 kg. The highest of the six measurements was used in statistical analysis. Grip strength of <16kg in females and <27kg in males indicate muscle weakness (Dodds et al., 2014).

Nutrition status was assessed using the MNA-SF, a screening tool which consists of six items (BMI, recent weight loss, stress or acute disease, mobility, neuropsychological problems, loss of appetite and difficulty eating). MNA-SF is validated in the older adult population across a range of settings (Kaiser et al., 2009). The scores indicate an individual's nutritional status; 'malnourished' (score 0-7), 'at risk of malnutrition' (score 8-11), or 'normal nutrition status' (score 12-14) (Kaiser et al., 2009). Residents' carers answered on their behalf when residents with cognitive decline were unable to respond.

Depressive symptoms were assessed using the GDS-15 which is a 15-item self-rating depression screening tool, validated in older adults, where scoring ranges from 1-15. The scores indicate the

depressive symptoms of older adults; 'normal to no depressive symptoms' (score 0-4), 'mild depression' (scores 5-9), 'moderate to severe depression' (score 10-15) (Yesavage & Sheikh, 1986).

QoL was assessed using the validated in older adults, SF-12 tool. The SF-12 is a 12-item measure of health and well-being, with two summary scales describing physical (physical component summary [PCS]) and mental well-being (mental component summary [MCS]) (Andrews, 2002). Lower MCS and PCS scores indicate greater disability such that >50 indicates no disability, 40-50 indicates mild disability, 30-40 indicates moderate disability and <40 indicates severe disability (Andrews, 2002).

Intervention

Residents were provided with the nutrient-dense ONS four times daily for 18-weeks. The ONS used in this study was a ready-made energy and protein dense liquid ONS (125 ml containing 300 kcal, 18 g protein: Fortisip Compact Protein, Nutricia, Australia) given in four 60 ml doses. The registered nurses/care givers dispensed 60 ml of the ONS into glasses with increments of 15 ml, 30 ml, 45 ml, and 60 ml, to residents while completing their regular medication rounds at 8am, 12pm, 5pm and 7pm daily. When fully consumed, the ONS provided residents with 576 kcal and 35 g protein daily in addition to their dietary intake. Participant compliance was monitored by nurses who noted on a tracking sheet (Appendix B) whether residents consumed 60 ml, 45 ml, 30 ml, 15 ml, or none of the ONS. If the amount consumed was <60 ml, nurses noted the reason why. All residents were provided with the flavour 'neutral' with the option to change to mocha if they did not enjoy the neutral taste. Compliance was calculated as the amount of ONS consumed compared to the amount of ONS that was provided.

Data analysis

Statistical analysis was carried out using SPSS statistical software (Version 27, SPPS Inc., Chicago, IL, USA). The normality of data was assessed using the Shapiro Wilk and Kolmogorov-Smirnov tests. Parametric data were presented as mean and standard deviation and non-parametric data were presented as median with 25^{th} and 75^{th} percentiles. Per protocol analysis was used in this analysis as four of the 12 residents who did not complete this study passed away preventing any post intervention measures being taken. Data from baseline and post-intervention measurements of per protocol residents were compared using dependent sample t-test for parametric data and Wilcoxon Signed-Rank test for non-parametric data. Baseline characteristics of per protocol residents and dropouts were compared using independent samples t-test for continuous normally distributed data and chi-squared test for categorical variables. Baseline characteristics and pre and post intervention measures of responders (residents who gained weight) and non-responders (residents who did not gain/lost weight) were compared using independent samples t-test for continuous normally distributed data

and chi-squared test for categorical variables. Effect size between pre and post intervention data were calculated. For normally distributed data the t-value divided by square root of sample size was used to calculate effect size and for non-normally distributed data Z-value divided by the square root of the sample size was used. Significance was set at p=0.05 for all analyses.

Results

Details of the participant recruitment and participation in the study are shown in Figure 1. Of the 50 residents invited to participate in the study, 32 residents consented and began the study, and 20 residents completed the 18-week intervention.

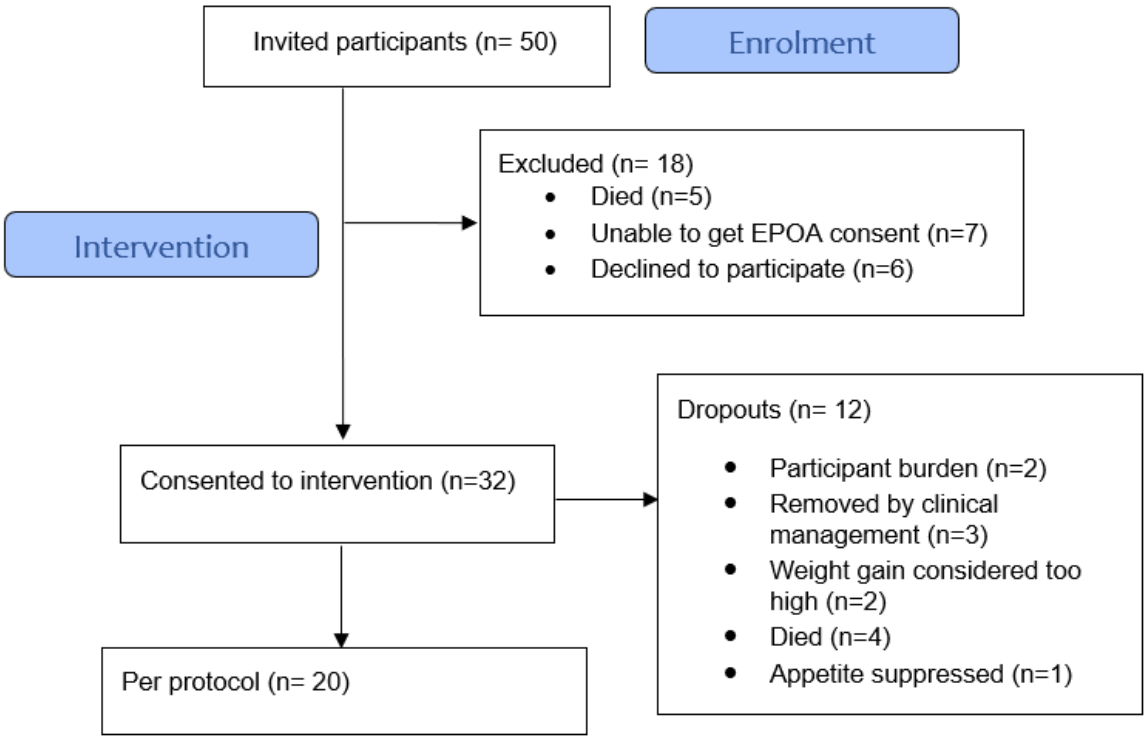

Figure 1: Participant Recruitment

Participant characteristics

Residents' mean age was 86.7 ± 6.8 years, 50% were women and 60% were living in hospital level of care. Of all residents, 20% were categorised as malnourished and 80% categorised as at risk of malnutrition. Table 5 details the characteristics of the residents. There was no significant difference in the characteristics of per protocol residents and those who did not complete the intervention (Appendix A).

Table 5. Participant characteristics

Characteristics	
Age (years) mean ± SD (range)	86.7 ± 6.8 (75-103)
	n (%)
<85 years	11 (55.0)
≥85 years	9 (45.0)
Sex	
Men	10 (50.0)
Women	10 (50.0)
Level of Care	
Rest home	8 (40.0)
Hospital	12 (60.0)
Previous living setting	
Home	12 (66.7)
Hospital	6 (33.3)
Ethnicity	
New Zealand European	18 (90.0)
*Other	2 (10.0)
Relationship status	
Married/Partnered	8 (42.1)
Never married/widowed	11 (57.9)
Level of education	
Primary and Secondary	9 (53.0)
Tertiary	8 (47.0)
Health (mean ± SD (range))	
Number of Comorbidities,	6.0 ± 2.7 (1-12)
Number of medications	7.5 ± 3.3 (3-15)
Nutrition status	
MNA-SF score, median [25th, 75th percentile]	9.0 [7.3, 10.0]
Malnourished, MNA-SF score n (%)	5 (20.0)
At risk of malnutrition, MNA-SF score n (%)	15 (80.0)

*Ethnicity, Other: Māori n=1, Fijian n=1

Abbreviations: MNA-SF – Mini Nutritional Assessment Short Form

Following the 18-week intervention (mean ± SD) body weight (1.5 ± 5.9 kg (*p*=0.259, *d*=0.260)) and BMI (0.5 ± 2.1 kg/m^2 (*p*=0.335, *d*=0.220)) increased in 65% (13/20) of residents. Mean total body fat (1.4 ± 6.6 kg (*p*=0.679, *d*=0.103)) and body fat percentage (1.3 ± 7.5% (*p=0.506, d*=0.171)) increased in 63% (10/16) of residents, while muscle mass (0.8 ± 2.2 kg (*p*=0.137, *d*=0.390)) increased in 56% (9/16)

of residents. A larger proportion of residents aged ≥90 than <90 years had an increase in their total body fat and body fat percentage (83% vs. 50%). Post intervention (median [25th, 75th percentile]) MNA-SF score (10 [8.3, 11]) increased (1 [-1, 1] (*p=0.197, d*=0.288*)*) in 65% (13/20) of residents. As a result, 10% of residents were categorised as malnourished, 65% categorised as at risk of malnutrition and 25% were categorised as having a normal nutrition status. A larger proportion of residents whose nutritional status improved had an increase in weight and BMI than those whose nutritional status did not improve (77 vs. 43%, *p*=128 for both weight and BMI). Despite these improvements there were no significant changes (*p*=<0.05) and effect size was small (*d*=0.2).

Residents who gained weight (n=7, responders) and those who did not gain weight (n=13, non-responders) were compared. Gender (*p*=0.019), baseline fat free mass (*p*=0.041), baseline muscle mass (*p*=0.046) and baseline body fat percentage (*p*=0.036) had a significant effect on whether residents responded to the intervention. Six of the seven non-responders were women, with non-responders having on average 8.4 kg of fat free mass and 4.7 kg of muscle mass less than responders and 4.9% higher body fat percentage than responders. Post-intervention weight was the only significant factor between responders and non-responders (*p*=0.047), with non-responders weighing on average 12 kg less than responders, there was no significant difference in compliance between responders and non-responders (Appendix B- Table to compare responders (gained weight) and non-responders (no weight gain)).

Table 6 shows the impact of the intervention on body composition and physical function. BIA measures were unable to be taken on four residents (pacemaker n=2, ataxic n=1, above knee amputation n=1). At baseline, two residents were unable to complete the grip strength measure due to limited cognition, and at follow up six residents declined due to limited cognition or agitation.

Table 6. The impact of the ONS intervention on body composition, nutrition status and function (Pre and post anthropometric measures)

Characteristics	Baseline	Post intervention	Change from baseline	*P*-value
Anthropometrics				
Weight (kg)	61.2 ± 13.2	62.7 ± 15.7	1.5 ± 5.9	0.259
BMI (kg/m^2)	22.9 ± 3.6	23.4 ± 4.1	0.5 ± 2.1	0.335
<23 kg/m^2, n (%)	9 (45)	10 (50)		
23-30 kg/m^2, n (%)	11 (55)	9 (45)		
>30 kg/m^2, n (%)	0 (0)	1 (5)		

Fat Free Mass (kg), mean ± SD	41.1 ± 8.1	42.3 ± 9.6	1.2 ± 3.7	0.207
Muscle mass (kg), mean ± SD	21.3 ± 4.7	22.1 ± 5.4	0.8 ± 2.2	0.137
Total Body Fat (kg), mean ± SD	20.1 ± 10.3	21.5 ± 9.4*	1.4 ± 6.6	0.679
Body fat percentage, mean ± SD	31.8 ± 11.3	33.1 ± 9.3	1.3 ± 7.5	0.506
Function				
Max. grip strength (kg), mean ± SD	13.7 ± 8.0	13.1 ± 8.4	-1.4 ± 5.6	0.396
Normal muscle strength, n (%)	5 (27.8)	2 (16.7)		
Low muscle strength, n (%)	13 (72.2)	10 (83.3)		

*non-parametric data shown as a mean to ease comparison

Abbreviations: BMI – Body Mass Index

We observed a high level of overall median compliance with 98.6% of prescribed ONS being consumed. The 8 am dose had the highest rates of median compliance (100%), followed by the 5pm (99.6%), 12pm (99.2%) and then 7pm (96.8%) doses. The most common reasons for not consuming the whole dose were not liking the taste, being unwell and being asleep. (A full breakdown of compliance is in Appendix A). With levels of compliance at 98.6% the assumption is that of the 240 ml of ONS provided daily, 237 ml were consumed providing 568 kcal and 34 g of protein.

Table 7 shows the impact of the intervention on mental and physical wellbeing. There was a non-significant median improvement in scores of all three measures. Geriatric Depression Score (median [25th, 75th] -1 [-3.5, 1.0], SF-12 MCS score (mean $\pm$ SD) +2.8 ± 12.0 and SF-12 PCS score +5.9 ± 11.1. Not all residents were able to complete these measures due to cognitive decline.

Table 7. The impact of the ONS intervention on mental and physical wellbeing

Characteristics	Pre intervention	Post intervention	Change from baseline	*P-value*
GDS-15 score, median [25th, 75th percentiles]	5.0 [2.0, 7.0]*	3.0 [0.5, 5.5]	-1 [-3.5, 1.0]	0.225
Normal, n (%)	7 (43.8)	7 (70)		
Mild depression, n (%)	9 (56.3)	2 (20)		
Moderate to severe depression, n (%)	0 (0)	1 (10)		
SF-12 MCS score, median [25, 75 percentiles]	53.3 [44.7, 58.9]*	56.0 [49.9, 61.4]	2.8 ± 12.0	0.953
No disability, n (%)	7 (63.6)	11 (78.6)		

Mild disability, n (%)	3 (27.3)	2 (14.3)		
Moderate disability, n (%)	1 (9.1)	1 (7.1)		
SF-12 PCS score, n=14, median [25, 75 percentiles]	38.40 [33.3, 41.8]*	47.6 [34.9, 52.1]	5.9 ± 11.1	0.264
No disability, n (%)	1 (10)	4 (30.8)		
Mild disability, n (%)	4 (40)	5 (38.5)		
Moderate disability, n (%)	3 (30)	2 (15.4)		
Severe disability, n (%)	2 (20)	2 (15.4)		

*Parametric data shown as median [25, 75] to ease comparison

Abbreviations: GDS-15-Geriatric Depression Scale

SF-12 - Medical Outcomes Study 12-item Short Form Health Survey

MCS- Mental Component Summary

PCS-Physical Component Summary

Discussion

This pilot study is the first to investigate outcomes of and compliance to a compact, energy dense ONS (Fortisip Compact Protein, Nutricia, Australia) using the Med Pass protocol among RAC residents in New Zealand. We observed compliance (volume of prescribed ONS consumed) to be high at 98.6%. A similar intervention in Germany provided the same volume of energy dense ONS as the current study, but as two 125 ml bottles (Fortimel Compact, Nutricia GmbH; 125 ml, 24 g protein and 300 kcal/ bottle; 2.4 kcal/ ml) daily over a 12-week period, rather than in four 60 ml doses (Jobse et al., 2015). In that study, median compliance of 82% in per protocol analysis was reported (Jobse et al., 2015). A study in the UK which also provided two ONS bottles daily in a combination of energy densities (125 ml, 2.4 kcal/bottle and 200 ml, 1.5 kcal/ bottle) and had a lower compliance level of 63% (Stow et al., 2015). It is likely that the higher levels of compliance in the current study were a result of the Med Pass protocol combined with the benefits of a high energy density ONS in small tolerable doses.

Despite non-significant findings (*p>0.05)*, the current pilot study resulted in improved anthropometric measures. Weight, BMI, fat free mass and muscle mass all improved following the 18-week ONS intervention. The increase in muscle mass from baseline to post intervention was the measure nearest to reaching significance and showed a small-medium effect size, which suggests that, with a greater number of residents significance may have been reached. In a 24-week RCT of 81 Taiwanese RAC residents (n=47 in the intervention group, n=43 completed the study) an ONS intervention (50 g/day; 9.5 g protein; 250 kcal) also resulted in significant increases in muscle mass (Lee et al., 2013). Also reported were increased mid-arm circumference (0.17 $\pm$ 1.02 cm, *p<0.001*), calf circumference (0.43

± 1.44 cm, *p<0.01*) and grip strength of (+1.04 kg) (Lee et al., 2015; Lee et al., 2013). These findings suggest that a sample size of approximately 43 residents would be required show significant findings and that body composition changes associated with ageing could be reversed with effective nutrition intervention.

In the present study, maximum grip strength was the only measure that did not improve over the 18-week intervention despite a mean increase in muscle mass. This is in contrast to findings from a cross-sectional study of 2647 individuals aged 50 years and older (mean age 62.6 years, 52.9% women) in the USA which concluded that muscle mass and strength were positively correlated after adjusting for age and gender (Chen, Nelson, Zhao, Cui, & Johnston, 2013). However, as only 38.5% of these residents were older adults these findings may not be generalisable to the older adult population (Chen et al., 2013). The Health, Aging and Body Composition Study investigated changes in muscle mass and strength of 1880 older adults over a three-year period in the USA (Goodpaster et al., 2006) It was found that loss of muscle strength was much more rapid than the loss of muscle mass and that increases in lean mass were not accompanied by strength maintenance or gain (Goodpaster et al., 2006). These losses have been estimated to be ~1% loss of muscle mass and ~3% loss of strength annually after the age of 60 years (Oikawa, Holloway, & Phillips, 2019). To limit inactivity-mediated losses of function in older adults, it is suggested that moderate amounts of high quality protein should be consumed with each meal, and that habitual exercise should be incorporated into everyday life (English & Paddon-Jones, 2010). While residents were not on bed rest during the current study, for the final 30-days of the intervention New Zealand was under COVID-19 Lockdown restrictions. These restrictions prevented the RAC residents completing their normal levels of physical activity as exercise facilitators could no longer enter the RAC, and residents were discouraged from leaving the RAC for any reason. A reduction in physical activity may have exacerbated residents' reduction in grip strength. It is important that losses in strength are prevented or reversed as, with each period of inactivity, it is likely that further strength will be lost, resulting in reduced function (Clark & Manini, 2010). In the current study, function measured using the 2.4-m walking test at baseline, was not able to be followed up post-intervention due to the COVID-19 lockdown restrictions where all measures were taken outside on a paved surface which was deemed unsafe for completing the 2.4-m walking test.

Weight was the measure used to determine if residents were responders or non-responders to the intervention as, in RAC, weight is routinely assessed to determine whether ONS supplementation is required. Despite non-responders not gaining weight over the 18-week intervention, non-significant changes in body composition were observed post-intervention. In the non-responder group, there was an average 0.8 kg increase in fat free mass (35.9 kg baseline vs. 36.7 kg post intervention), 0.7 kg increase in muscle mass (18.3 kg baseline vs. 19.0 kg post intervention) and 4% decrease in body fat

percentage (39.5% baseline vs. 35.5% post intervention). These findings suggest that while 'non-responders' did not gain weight, positive changes in body composition were still occurring.

Previous studies have found that use of ONS improves the QoL of older adults in RAC (Gariballa & Forster, 2007; Lee et al., 2015; Parsons et al., 2017). It is suggested that this increased QoL is brought about in part due to improvements in micronutrient status, specifically vitamin B12 and folate levels. Deficiencies in vitamin B12 and folate levels have been linked to geriatric depression which is associated with physical and social decline (Fiske et al., 2010; Tiemeier et al., 2002). The ONS regime used in the current study provided residents with 2.8 μg Vitamin B12 (>100% RDI for older adults) and 200 μg folic acid (~50% RDI for older adults) (Ministry of Health, 2013). It is therefore possible that the improvements in GDS-15 and SF-12 scores in the current study were in part due to the residents' increased micronutrient consumption.

Post intervention, the median MNA-SF score remained within the range for 'at risk of malnutrition' (Kaiser et al., 2009). Of the six items in this screening tool, four have previously been shown to be positively impacted by ONS; weight, BMI, appetite and mobility (Gariballa & Forster, 2007; Gazzotti et al., 2003; Lauque et al., 2000; Lee et al., 2015; Lee et al., 2013; Pouyssegur et al., 2015; Smith et al., 2020). The other two items refer to psychological stress or acute disease in the last three months (yes/no) and neuropsychological problems (severe dementia or depression/ mild dementia/ no psychological problems). While the current intervention has shown that depressive symptoms may be improved using ONS, dementia cannot be improved using ONS. Use of ONS can also not mitigate whether psychological stress or acute disease is experienced. As a result, the MNA-SF screening tool items referring to neuropsychological problems and psychological stress/acute disease could not have been positively impacted using ONS, potentially preventing a greater difference in total MNA-SF scores pre and post intervention in the current study.

In the RAC in which the present study was carried out timing of the medication rounds coincided with resident mealtimes. As a result the ONS was provided to the residents along with their meals. This protocol does not adhere to Dietetics Association of Australia guidelines that suggest ONSs should not be provided with meals (Watterson et al., 2009). Evidence suggests that total energy consumption is higher when ONS are provided one hour before meal times rather than at meal times (Wilson, Purushothaman, & Morley, 2002). As median compliance to the ONS protocol was 98.6%, it is likely that dietary intake could have been negatively impacted. This was the case for one participant who found that the ONS was reducing their meal intake and they did not complete the study. Given the high level of compliance in the current study, it may be worthwhile investigating the impact of ONS timing on meal intake to quantify whether providing ONS at mealtimes does in fact, reduce meal

intake. The small sample size (exacerbated by the high dropout rate) of the study is a limitation and potential explanation as to why the findings did not reach significance. While the inclusion of cognitively declined residents increased the generalisability of results (Taylor, DeMers, Vig, & Borson, 2012), the many cognitively declined residents were unable to respond to the SF-12 and GDS-15 questionnaires, further reducing the responses from an already limited sample. At baseline, residents were given the option to complete the questionnaires in their room or in a communal living area. However post-intervention, all measures were completed outdoors (due to RAC COVID-19 requirements), which resulted in some residents becoming agitated and declining to answer the questionnaires. The reduced number of residents completing the post intervention questionnaires weakens any comparison to baseline measures. Due to the 10-week recruitment period, there was a delay of up to 10-weeks for some residents from providing consent and having baseline measures taken, until the intervention began. This may have reduced the accuracy of baseline data, as it is likely that some of the measures could have changed over the intervening 10 weeks. A further limitation to the study is that BIA measures were carried out regardless of whether a meal had been eaten in the last two hours, which may have impacted the results.

To monitor levels of compliance in the study the researcher was in regular contact with the nursing staff at the RAC. Meaning that anytime the reason for not consuming the full 60 ml of the ONS was not noted on the tracking sheet, the researcher clarified with nursing staff as to why the full dose was not consumed, increasing the precision of findings This is a strength of the study as it relayed to the nursing staff the importance of providing the ONS to the residents. It also meant that reasons for not consuming the full 60 ml of the ONS noted on the tracking sheet could be addressed by the researcher and nursing stuff. A further strength of this study was that the MNA-SF of cognitively declined residents was assessed by nursing staff and medical records. This helps to increase the generalisability of the findings as cognitively declined older adults are often excluded from research despite making up a large proportion of those in RAC and are often at higher nutritional risk than older adults without cognitive or physical impairment (Jobse et al., 2015; Taylor et al., 2012).

Conclusion

We found compliance to a new nutrient- and energy dense ONS using the Med Pass protocol was 98.6%, demonstrating its acceptability among RAC residents in New Zealand. We observed an improvement in nutrition risk status, weight, muscle mass, GDS-15 score and SF-12 score. Providing nutrient and energy dense ONSs using the Med Pass protocol may be an effective method of improving

nutrition status in RAC residents and warrants further investigation among a larger group of RAC residents.

Chapter 4- Conclusion- Recommendations

The aim of this study was to determine whether 60 ml of a new compact ONS consumed four times daily with the medication round (Med Pass protocol) for 18 weeks was effective in improving nutrition status and physical and QoL measures of nutritionally at-risk RAC residents. A secondary aim was to determine levels of compliance to the compact ONS following the Med Pass protocol.

Objective one referred to collecting baseline measures of older adults identified as malnourished or at risk of malnutrition. Nutrition status was determined using the MNA-SF score. Five (20%) residents were identified as 'malnourished' (score 0-7) and 15 (80%) residents were identified as 'at risk of malnutrition' (score 8-11), with the median [25^{th} , 75^{th} percentile] score of 9.0 [7.3 , 10.0] out of a maximum score of 15. The mean age was 86.7 ± 6.8 years, 50% were women and 60% were living in hospital level of care. The mean weight of residents at baseline was 61.2 kg and mean BMI was 22.9 kg/m^2. The mean muscle mass of residents at baseline was 21.3 kg, mean total body fat was 20.1 kg and mean body fat percentage was 31.8%. The mean maximum grip strength at baseline was 13.7 kg. Grip strength of <16kg in females and <27kg in males indicates muscle weakness (Dodds et al., 2014), as a result 72.2% of residents had a baseline grip strength indicating muscle weakness. While all the measures produced normally distributed data it is acknowledged that using the mean as a measure of central tendency may be misleading due to the small sample size. The median SF-12 MCS score at baseline was 53.3 and the median SF-12 PCS score was 38.40. Lower MCS and PCS scores indicate greater disability such that >50 indicates no disability, 40-50 indicates mild disability, 30-40 indicates moderate disability and <30 indicates severe disability (Andrews, 2002), therefore the SF-12 MCS score indicated 'no disability' and the SF-12 PCS score indicated 'mild disability' in baseline measures. The median GDS-15 score at baseline was 5. This score indicated 'mild depression' in the baseline measures as scores 0-4 indicate 'normal to no depressive symptoms, scores 5-9 indicate 'mild depression' and scores 10-15 indicate 'moderate to severe depression' (Yesavage & Sheikh, 1986).

Objective two referred to determining the overall volume, energy and protein of ONS consumed by the 20 participants over the 18-week trial. This was achieved by determining the median level of compliance (98.6%) and then calculating 98.6% of the ONS prescribed and the energy and protein that was provided. It was calculated that of the prescribed 240 ml, residents' mean intake was 237 ml providing a supplementary mean energy intake of 568 kcal and protein intake of 34 g each day.

Objective three referred to determining levels of compliance to the ONS protocol and monitoring reasons for not consuming the whole amount. Levels of compliance were determined by dividing the

amount of ONS the participants consumed by the amount that was prescribed. Overall median compliance was 98.6%, the most common reasons for not consuming the whole dose were not liking the taste, being unwell and being asleep.

Objective four referred to determining whether there had been improvements in the baseline measures after the 18-week intervention. Post intervention (median [25th, 75th percentile]) MNA-SF score (10 [8.3, 11]) increased (1 [-1, 1] (*p*=0.197, *d*=0.288*)* in 65% (13/20) of residents. As a result, 10% of residents were categorised as malnourished compared to 20% at baseline, 65% categorised as at risk of malnutrition compared to 80% at baseline and 25% were categorised as having a normal nutrition status compared to none at baseline. Anthropometric measures (mean ± SD) body weight (1.5 ± 5.9 kg (*p*=0.259, *d*=0.260)) and BMI (0.5 ± 2.1 kg/m^2 (*p*=0.335, *d*=0.220)) increased in 65% (13/20) of residents. Despite these improvements there were no significant changes (*p*=<0.05) and effect size was small (*d*=0.2).

Regarding body composition, mean total body fat (1.4 ± 6.6 kg (*p*=0.679, *d*=0.103)) and body fat percentage (1.3 ± 7.5% (*p*=0.506, *d*=0.171)) increased in 63% (10/16) of residents, while muscle mass (0.8 ± 2.2 kg (*p*=0.137, *d*=0.390)) increased in 56% (9/16) of residents. There was a non-significant decrease of -1.42 ± 5.55 kg in grip strength. Depressive symptoms and QoL measures improved with a decreased median [25th, 75th percentiles] GDS-15 score of -1 [-3.5, 1.0], and an increase in (mean ± SD) SF-12 MCS score (2.78 ± 12.0) and SF-12 PCS score (5.9 ± 11.1).

The hypothesis for this study is that providing RAC residents identified to be at risk of malnutrition or malnourished with a new compact ONS four-times daily over 18 weeks will reduce rates of malnutrition. This hypothesis was met as median nutrition status (MNA-SF scores) improved by 10% (+1 [-1, 1], *p=0.197, d*=0.288) post intervention.

Interventions to reverse malnutrition and improve nutrition status of older adults are of great importance as when left untreated, malnutrition in older adults is associated with deteriorating health and increased health costs (Australian & New Zealand Society for Geriatric Medicine, 2019). Preliminary New Zealand based findings suggest rates of malnutrition in older adults are highest in recent admission to RAC compared to recent hospital admission or living in the community ((47% vs 23% vs 2%, respectively) (Wham et al., 2017). RAC is also the setting in which the majority of New Zealand DHB spending on older adults is utilised (Ministry of Health, 2016). This highlights the importance of focusing on improving nutrition status in RAC as it has the potential to help older adults to maintain their weight, muscle mass, strength and function. Improvements in these areas could result in a reduction in DHB spending on older adults.

The Arvida Group RAC facility, Aria Gardens, where the study was undertaken, seek to attain best practice nutrition care for their residents, and have an Eating Well Strategy. The high levels of compliance in the current pilot study indicate that this nutrition intervention using an energy and protein dense ONS following the Med Pass protocol is largely acceptable to older adults living in this RAC facility in Auckland. The positive changes in MNA-SF, SF-12 and GDS-15 observed in this study indicate that improvements in nutrition status and mental and physical wellbeing can be achieved through following this protocol. While these are only pilot findings further research into this area may help determine how ONS are best supplied to older adults in RAC to bring about improvements in residents' health. The Arvida Group has been provided with these findings and there is a possibility that the current intervention will continue to be used in the RAC because of these initial positive findings.

To monitor levels of compliance in the study the researcher was in regular contact with the nursing staff at the RAC. This is a strength of the study as it relayed to the nursing staff the importance of providing the ONS to the residents. It also meant that anytime the reason for not consuming the full 60 ml of the ONS was not noted on the tracking sheet, the researcher clarified with nursing staff as to why the full dose was not consumed, increasing the precision of findings. A further strength of this study was that the MNA-SF of cognitively declined residents was assessed via nursing staff and medical records rather than relying on potentially inaccurate responses from cognitively impaired residents. This increases the generalisability of the findings as cognitively declined older adults are often excluded from research despite making up a large proportion of those in RAC and often being at more nutritional risk that older adults without cognitive or physical impairment (Jobse et al., 2015; Taylor et al., 2012).

In the RAC in which the present study was carried out timing of the medication rounds coincided with resident mealtimes. As a result the ONS was provided to the residents along with their meals. This protocol did not adhere to Dietetics Association of Australia guidelines that ONS should not be provided with meals (Watterson et al., 2009). Evidence suggests that total energy consumption is higher when ONS are provided one hour before meal times rather than at meal times (Wilson et al., 2002). As median compliance to the ONS protocol was 98.6%, it is likely that dietary intake could have been negatively impacted. This was the case for one participant who found that the ONS was reducing their meal intake and they did not complete the study. Given the high level of compliance in the current study, it may be worthwhile investigating the impact of ONS timing on meal intake to quantify whether providing ONS at mealtimes does in fact, reduce meal intake. The small sample size of 20 participants (exacerbated by the high dropout rate) of the study is a limitation and potential explanation as to why the findings did not reach significance. While the inclusion of cognitively

declined residents increased the generalisability of results (Taylor et al., 2012), the many cognitively declined residents were unable to answer the SF-12 and GDS-15 questionnaires, further reducing the responses from an already limited sample size. At baseline, residents were given the option whether to complete the questionnaires in their room or in a communal living area. However post-intervention, all measures were completed outdoors (due to RAC COVID-19 requirements), which resulted in some residents becoming agitated and declining to answer the questionnaires. The reduced number of residents completing the post intervention questionnaires weakens any comparison to baseline measures. Due to the 10-week recruitment period, there was a delay of up to 10-weeks for some residents from providing consent and having baseline measures taken, until the intervention began. This may have reduced the accuracy of baseline data, as it is likely that some of the measures could have changed over the intervening 10 weeks. A further limitation to study is that BIA measures were carried out regardless of whether a meal had been eaten in the last two hours, which may have impacted the results.

This pilot study provides helpful insights into best practice for nutrition care of older adults in RAC. The current pilot study brought about positive changes in nutrition status, weight, body composition, symptoms of depression and QoL in residents at risk of malnutrition or malnourished. It also demonstrated that using an energy and protein dense ONS following the Med Pass protocol is largely acceptable to older adults living in Auckland RAC. If the Arvida RAC facility continued to use the Med Pass protocol for at risk of malnutrition or malnourished residents it is possible that positive changes in these measures would be maintained or continue to improve. A final recommendation from this pilot study is that Aria Gardens continue to use the Med Pass protocol for residents who are 'at risk of malnutrition' or 'malnourished.'

Further recommendations are that the ONS intervention should be repeated with a larger sample and where possible designed as a RCT. This would provide an opportunity to compare the outcome of the current Med Pass protocol to standard care in the RAC facility and more robust evidence for the benefit of the Med Pass protocol. A further opportunity would be a follow up study to determine whether improvements in body composition, nutrition status and QoL as a result of the intervention were maintained.

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Appendix

Appendix A- Supplementary Results

Table 8. Comparison of drop out and per protocol participant characteristics

Characteristics	Per protocol participants (n=20)	Drop outs (n=12)	*P*-value
Age (years) mean ± SD	86.7 ± 6.8	84.0 ± 8.4	0.334
<85years, n (%)	11 (55)	1 (8.3)	
≥85years, n (%)	9 (45)	11 (91.7)	
Gender, n (%)			0.358
Male	10 (50)	8 (66.7)	
Female	10 (50)	4 (33.3)	
Level of care, n (%)			0.168
Rest home	8 (40)	2 (16.7)	
Hospital	12 (60)	10 (83.3)	
Prior Living Setting, n (%)			0.643
Home	12 (66.7)	7 (58.3)	
Hospital	6 (33.3)	5 (41.7)	
Ethnicity, n (%)			0.692
New Zealand European	18 (90)	11 (91.7)	
*Other	2 (10)	1 (8.3)	
Marital status, n (%)			0.122
Married/Partnered	8 (42.1)	4 (40)	
Never married/widowed	11 (57.9)	6 (60)	
Highest level of education, n (%)			0.893
Primary and Secondary	9 (53)	6 (60)	
Tertiary	8 (47)	4 (40)	
Medical conditions			
Number of Comorbidities, mean ± SD	6 ± 2.7	5.17 ± 4.0	0.491
Number of medications, mean ± SD	7.5 ± 3.3	7.42 ± 4.1	0.950
Anthropometrics			

Weight (kg)	61.2 ± 13.2	65.1 ± 17.0	0.469
BMI, kg/m^2	22.9 ± 3.6	23.9 ± 4.7	0.545
<23 kg/m^2, n (%)	9 (45.0)	5 (41.7)	
23-30 kg/m^2, n (%)	11 (55.0)	7 (58.3)	
Fat Free Mass, kg n=16, mean ± SD	41.1 ± 8.1	43.5 ± 9.5	0.511
Muscle mass, kg n=16, mean ± SD	21.30 ± 4.7	22.8 ± 5.8	0.469
Total Body Fat, kg n=16, mean ± SD	20.1 ± 10.3	19.6 ± 12.3	0.909
Body fat percentage, % n=16, mean ± SD	31.8 ± 11.3	28.6 ± 14.0	0.527
Dietary Factors			
MNA-SF score, median [25^{th}, 75^{th} percentile]	9.0 [7.3, 10.0]	9.50 [8.0, 10.0]	0.831
MNA-SF Category			
Malnourished, n (%)	5 (20)	2 (16.7)	
At risk of malnutrition, n (%)	15 (80)	10 (83.3)	
Functional measure			
Max. grip strength (kg) n=12, mean±SD	13.7 ± 8.0	13.5 ± 5.9	0.950
Mental and Physical Wellbeing			
GDS-15 scale n=14, mean ± SD	4.2 ± 2.5	7.11 ± 3.3	0.473
SF-12 MCS score 12, n=14, mean ± SD	51.2 ± 7.8	50.0 ± 9.3	0.389
SF-12 PCS score 12, n=14, mean ± SD	38.1 ± 8.5	34.8 ± 4.8	0.389

*Ethnicity, Other: Māori n=1, Fijian n=1

**Ethnicity, Other: Fijian n=1

Abbreviations

BMI-Body Mass Index

MNA-SF-Mini Nutritional Assessment-Short Form

GDS-15-Geriatric Depression Scale

SF-12- Medical Outcomes Study 12-item Short Form Health Survey

MCS-Mental Component Summary

PCS-Physical Component Summary

Table 9- Comparison of responders (gained weight) and non-responders (no weight gain)

Characteristics	Non responder (n=7, 35%)	Responder (n=13, 65%)	*P*-value
Age (years) mean ± SD	85.9 ± 5.0	87.1 ± 7.7	0.711
<85years, n (%)	4 (57.1)	5 (38.5)	
≥85years, n (%)	3 (42.9)	8 (81.5)	
Gender, n (%)			0.019
Male	1 (14.3)	9 (69.2)	
Female	6 (85.7)	4 (30.8)	
Level of care, n (%)			0.251
Rest home	4 (57.1)	4 (30.8)	
Hospital	3 (42.9)	9 (69.2)	
Prior Living Setting, n (%)			
Home	5 (71.4)	7 (63.6)	
Hospital	2 (28.6)	4 (36.4)	
Ethnicity, n (%)			0.299
New Zealand European	6 (85.7)	12 (92.3)	
*Other	1 (14.3) Māori	1 (7.7) Fijian	
Marital status, n (%)			0.960
Married/Partnered	3 (42.9)	5 (41.7)	
Never married/widowed	4 (57.1)	7 (58.3)	
Highest level of education, n (%)			0.689
Primary and Secondary	3 (60)	6 (50)	
Tertiary	2 (40)	6 (50)	
Medical conditions			
Number of Comorbidities, mean ± SD	7.0 ± 3.6	5.5 ± 2.1	0.240
Number of medications, mean ± SD	7.3 ± 2.6	7.6 ± 3.8	0.839
Baseline measures			
Anthropometrics			
Weight (kg)	56.9 ± 9.6	63.5 ± 14.6	0.302

BMI, kg/m^2	23.1 ± 2.8	22.9 ± 4.0	0.889
<23 kg/m^2, n (%)	3 (42.9)	6 (46.2)	
23-30 kg/m^2, n (%)	4 (57.1)	7 (53.8)	
Fat Free Mass, kg, mean ± SD	35.9 ± 6.9	44.3 ± 7.4	0.041
Muscle mass, kg, mean ± SD	18.3 ± 4.0	23.0 ± 4.3	0.046
Total Body Fat, kg, mean ± SD	23.2 ± 4.2	18.3 ± 12.6*	0.376
Body fat percentage, %, mean±SD	39.5 ± 4.6	27.4 ± 12.0*	0.036
Dietary Factors			
MNA-SF score, mean ± SD	8.7 ± 2.2	8.7 ± 2.1	0.722
MNA-SF Category, n (%)			
Malnourished	2 (28.6)	3 (23.1)	
At risk of malnutrition	5 (71.4)	10 (76.9)	
Functional measure			
Max. grip strength (kg), mean±SD	11.0 ± 6.3	15.5 ± 8.8	0.263
Mental and Physical Wellbeing			
GDS-15 score, mean±SD	2.5 ± 1.4	5.2 ± 2.4	0.165
SF-12 MCS score, median [25, 75 percentiles]	50.5 ± 9.6	52.2 ± 5.8	0.358
SF-12 PCS score, median [25, 75 percentiles]	39.3 ± 9.4	35.3 ± 8.5	0.350

*Not-normally distributed but shown as mean ± SD for ease of comparison

Post-intervention measures	Non-responders, n=7 (35%)	Responders, n=13 (65%)	*P*-value
Anthropometrics			
Weight, kg, mean ± SD	55.8 ± 6.5	67.8 ± 16.6	0.047
BMI, kg/m^2	22.7 ± 1.7	24.3 ± 4.4	0.182
<23 kg/m^2, n (%)	4 (57.1)	6 (46.2)	
23-30 kg/m^2, n (%)	3 (42.9)	6 (46.2)	
>30 kg/m^2	-	1 (7.7)	
Fat Free Mass, kg, mean ± SD	36.7 ± 8.8	45.7 ± 8.7	0.063

Muscle mass, kg, mean ± SD	19.0 ± 5.1	24.0 ± 4.9	0.069
Total Body Fat, kg, mean ± SD	19.8 ± 5.0	22.5 ± 11.4	0.587
Body fat percentage, %, mean±SD	35.5 ± 9.7	31.7 ± 9.2	0.440
Dietary Factors			
MNA-SF score, mean±SD	8.0 ± 4.1	9.8 ± 1.5	0.311
MNA-SF category, n (%)			
Malnourished	3 (42.9)	1 (7.7)	
At risk of malnutrition	3 (42.9)	10 (76.9)	
Normal nutrition status	1 (14.3)	2 (15.4)	
Functional measure			
Max. grip strength (kg), mean±SD	11.7 ± 4.9*	13.6 ± 9.5	0.753
Mental and Physical Wellbeing			
GDS-15 score, mean±SD	2.4 ± 1.1	4.0 ± 4.1	0.187
SF-12 MCS score, mean ± SD	54.0 ± 4.5	56.0 ± 9.9	0.374
SF-12 PCS score, mean ± SD	48.6 ± 9.9	40.2 ± 10.8*	0.374
Compliance			
Overall compliance, median [25, 75 percentiles] %	99.6 [96.2, 99.8]	97.8 [86.5, 99.7]	0.078
8am (breakfast) dose, median [25, 75 percentiles] %	99.6 [98.0, 100]	100 [96.0, 100]	0.407
12pm (lunch) dose, mean ± SD %	98.7 ± 1.4 98.4 [97.2, 100]**	99.2 [95.2, 99.6]	0.335
5pm (dinner) dose, median [25, 75 percentiles] %	100 [99.2, 100]	98.4 [96.4, 100]	0.107
7pm (bedtime) dose, median [25, 75 percentiles] %	99.2 [96.2, 99.8]	94.6 [68.0, 99.4]	0.098

*not normally distributed but shown as mean ± SD for ease of comparison

**normally distributed but shown as median for ease of comparison

Abbreviations

BMI-Body Mass Index

MNA-SF-Mini Nutritional Assessment-Short Form

GDS-15-Geriatric Depression Scale

SF-12- Medical Outcomes Study 12-item Short Form Health Survey

MCS-Mental Component Summary

PCS-Physical Component Summary

Table 10. ONS Compliance

Compliance	
Overall Compliance, median % [25th, 75th percentile] Range: 74.1-100%	98.6 [95.5, 99.8]
Does not like taste, % (n)	2.0 (203)
Unwell, % (n)	1.3 (130)
Asleep, % (n)	1.2 (123)
No appetite, % (n)	0.5 (47)
North shore hospital, % (n)	0.4 (38)
Difficulty swallowing, % (n)	0.3 (31)
Confusion/agitated, % (n)	0.2 (21)
Social leave, % (n)	0.1 (10)
Constipated, % (n)	0.0 (1)
8am (breakfast) dose, median % [25th, 75th percentile] Range: 89.2-100%	100 [97.3, 100]
Does not like taste, % (n)	1.3 (33)
North shore hospital, % (n)	0.4 (10)
No appetite, % (n)	0.2 (6)
Asleep, % (n)	0.1 (2)
Confusion/agitated, % (n)	0.1 (2)
Unwell, % (n)	0.1 (2)
Social leave, % (n)	0.0 (1)
12pm (lunch) dose, median % [25th, 75th percentile] Range: 84.9-100%	99.2 [95.9, 99.9]
Does not like taste, % (n)	1.8 (46)
No appetite, % (n)	0.5 (13)
North shore hospital, % (n)	0.4 (10)
Social leave, % (n)	0.2 (6)
Unwell, % (n)	0.2 (4)
Confusion/agitated, % (n)	0.1 (3)
Asleep, % (n)	0.0 (1)

Difficulty swallowing, % (n)	0.0 (1)
5pm (dinner) dose, median % [25th, 75th percentile] Range: 74.6-100%	99.6 [74.6, 100]
Does not like taste, % (n)	2.0 (51)
Unwell, % (n)	1.3 (32)
North shore hospital, % (n)	0.4 (9)
Confusion/agitated, % (n)	0.2 (4)
No appetite, % (n)	0.1 (2)
Social leave, % (n)	0.1 (2)
7pm (bedtime) dose, median % [25th, 75th percentile] Range: 19.8-100%	96.8 [90.7 , 100]
Asleep, % (n)	4.8 (120)
Unwell, % (n)	3.7 (92)
Does not like taste, % (n)	2.9 (73)
Difficulty swallowing, % (n)	1.2 (30)
No appetite, % (n)	1.0 (26)
Confusion/agitated, % (n)	0.5 (12)
North shore hospital, % (n)	0.4 (9)
Social leave, % (n)	0.0 (1)
Constipated, % (n)	0.0 (1)

Participant Information Sheet

MASSEY UNIVERSITY
COLLEGE OF HEALTH
TE KURA HAUORA TANGATA

Phase Two: Oral Nutrition Supplement (ONS)

Study title: Eating Well in Rest Home Care

Locality: Arvida Village

Ethics committee ref.: 20/NTB/120

Sponsor: Massey University

Lead investigator: Professor Carol Wham

Phone: 09 213 6644

You are invited to take part in an Oral Nutrition Supplement study to improve your nutrition intake. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether you will participate in this study. Before you decide you may want to talk about the study with other people. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep. This document is 5 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

What is the purpose of the study?

The purpose of this study is to explore whether a new Oral Nutrition Supplement "Fortisip Compact" can improve nutrition as well as physical health (such as body weight and composition) and psychological health and wellbeing.

This study will determine the acceptability and effectiveness of an oral nutrition supplement. The outcome will help inform best practice for nutrition care by the Arvida Group and other aged care

providers. This study is being undertaken by the department of Nutrition and Dietetics at Massey University in Albany and is led by Professor Carol Wham who can be contacted by calling 09 213 6644.

What will my participation in the study involve?

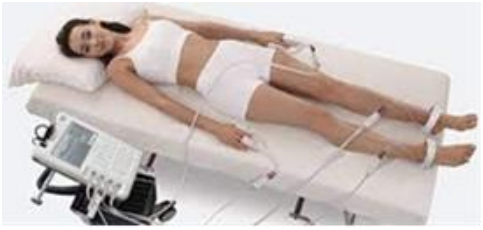
If you agree to take part in the study, you will be receiving an oral nutrition supplement (60mls) four times a day for 90 days. The supplement will be administered with the medication round by a medication competent registered nurse or senior caregiver in a 60ml glass. The total consumed will be recorded in increments such as ¼, ½ or ¾ or full.

At the end of the intervention (about 12 weeks) the surveys and physical measures from Phase one of the study will be repeated to assess whether there has been any change.

A dietetic researcher will assess your nutrition status using a 6-item survey, the Mini Nutritional Assessment Short-form. You will be invited to complete four short surveys to assess your risk of swallowing difficulty (dysphagia), your health-related quality of life, any risk of depression and a Mealtime Satisfaction Survey. Your demographic and health data will be obtained from the rest home clinical notes to record your medications, co-morbidities, weight, height (if available) and any recent falls or fractures.

The dietetic researcher will then undertake some physical measures including your hand grip strength using a hand dynamometer, and your usual walking speed by measuring how long it takes you to walk 2.4 meters (or 8 feet). Your muscle mass and fat mass will then be measured while you are lying down using portable bioelectrical impedance assessment (BIA) scales. The scales send a harmless electrical current up through your body to "read" the amount of fat body mass and lean body mass calculating your percentage of body fat.

Hand grip strength using a hand dynamometer



Muscle mass and fat mass measure using portable bioelectrical impedance assessment (BIA) scales.

What are the possible benefits and risks of this study?

We do not envisage any risks or discomfort to yourself by taking part in the study. This oral nutrition supplement is ready to drink, high energy, high protein, and low volume to maintain body weight and muscle mass. It has only half of the volume of conventional supplements and has been shown to be more acceptable in studies overseas. You will required to stop taking any other oral nutrition supplement or protein drink and will be monitored during this time to ensure your weight is maintained.

Who pays for the study?

Participants will not incur any costs.

What if something goes wrong?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

What are my rights?

Participation in this study is voluntary and you are free to decline to participate, or to withdraw from the research at any practicable time, without experiencing any disadvantage. You also have the right to access information collected as part of the study. All information collected will be de-identified to protect your privacy and confidentiality.

What happens after the study or if I change my mind?

All information will be stored in password protected computers accessible only by the investigators. Only the investigators will have access to the complete data set. Investigators are aware and will comply with all Privacy Act tenets and requirements. Information will be stored as de-identified numbers with no individual information reported. The Health (Retention of Health Information) Regulations 1996 require that some health information be retained for a period of ten years.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Professor Carol Wham

Telephone number: 09 213 6644

Email: c.a.wham@massey.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Māori Heath support, please contact:

Dr Bevan Erueti, Associate Dean – Māori, Massey University

Telephone number: (06) 356 9099 ext. 83087

Email: B.Erueti@massey.ac.nz

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC

Email: hdecs@health.govt.nz

Consent Form

Please tick to indicate you consent to the following

Consent Form

MASSEY UNIVERSITY
COLLEGE OF HEALTH
TE KURA HAUORA TANGATA

I have read or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given enough time to consider whether to participate in this study.		
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes o	No o
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes o	No o
I consent to my personal health records being released to the research team by the Clinical Manager.	Yes o	No o
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		
I understand the compensation provisions in case of injury during the study.		
I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
I wish to receive a summary of the results from the study.	Yes o	No o

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date:

Tracking Sheet

Resident name:	1.Please record Dose i.e. amount consumed as 15ml or 30ml or 45ml or 60ml 2.Please record reason for resident not drinking all of the 60ml.				
Date: **e.g. Mon 24/05/2021**	**Dose (ml)**				**Reason for drinking less than 60ml e.g. no appetite**
	Breakfast	**Lunch**	**Dinner**	**Bedtime**	